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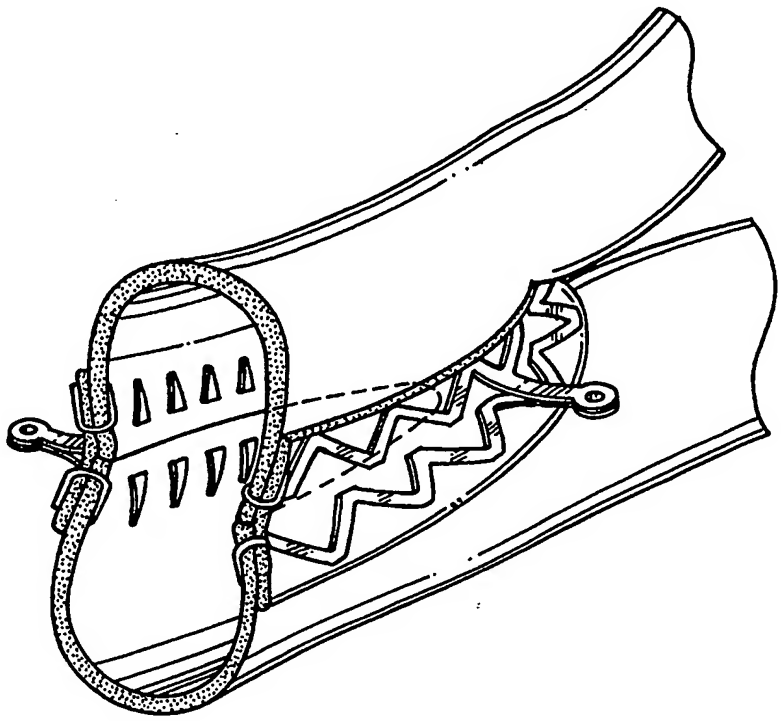
(54) Title: MEANS AND METHOD FOR PERFORMING AN ANASTOMOSIS

(57) Abstract

An anastomosis is performed using a mounting structure mounted on the outside of at least one vessel. The mounting structure includes a flexible mounting structure that is attached to the vessel by a special instrument. A graft vessel is attached to the mounting structure either directly or by means of another mounting structure attached to the graft vessel. Tools for attaching a mounting structure to a vessel are disclosed, and a tool for attaching two mounting structures together is also disclosed. Methods for carrying out the anastomosis according to the invention are also disclosed.



MEANS AND METHOD FOR PERFORMING AN ANASTOMOSIS

Technical Field of the Invention

The present invention relates to the general art of surgery, and to the particular field of means and methods associated with anastomoses.

Background of the Invention

In the United States, there are currently as many as 300,000 coronary artery bypass graft (CABG) procedures performed on patients annually. Each of these procedures may include one or more graft vessels which are hand sutured. Until recently, coronary artery bypass procedures have been performed with the patients on cardiopulmonary bypass whereby the heart is stopped with cardioplegia and the surgery is performed on an exposed, stationary heart.

The vast majority of CABG procedures performed currently are accomplished by opening the chest wall to gain access to the coronary vessels. Through the use of heart lung bypass machines and a drug to protect the heart muscle, the heart is stopped and remains still during the procedure. In this setting, the surgeon has ample time and access to the vessels to manipulate hand suturing instruments such as forceps, needle holders and retractors.

However, with increasing costs of hospital stays and increased awareness by patients of other minimally invasive surgical procedures, interest in developing a minimally invasive CABG procedure is increasing. Hospitals need to reduce costs of procedures and patients would like less post-operative pain and speedier recovery times.

In the past, two significant developments in the technology played a major role in advancing the whole

perform the procedure and reduces the cost of the operation by eliminating the heart lung bypass machine.

In the case of minimally invasive procedures on a beating heart, the surgeon starts by making a mini-thoracotomy between the fourth and fifth ribs and, sometimes, removing the sternal cartilage between the fourth or fifth rib and the sternum. The space between the fourth and fifth ribs is then spread to gain access to the internal mammary artery (IMA) which is dissected from the wall of the chest. After dissection, it is used as the blood supply graft to the left anterior descending artery of the heart (LAD). Below the IMA lies the pericardium and the heart. The pericardium is opened exposing the heart. At this point, the LAD may be dissected from the fissure of the heart and suspended up with soft ligatures to isolate the artery from the beating heart. Some companies are making a special retractor to gently apply pressure to the heart muscle to damp the movement right at the LAD. A small arteriotomy is performed in the LAD and the graft IMA is sutured to the LAD.

Traditionally, to gain access to the cardiac vessels to perform this procedure the sternum is sawn in half and the chest wall is separated. Although this procedure is well perfected the patient suffers intense pain and a long recovery.

Until recently all bypass graft procedures have been performed by hand suturing the tiny vessels together with extremely fine sutures under magnification. The skills and instruments required to sew extremely thin fragile vessel walls together have been perfected over the last twenty years and are well known to the surgical community that performs these procedures.

anastomosis without requiring the stopping of a beating heart. Still further, there is a need for performing such an anastomosis in a minimally invasive manner.

The current method of hand suturing is inadequate for the following reasons:

On a beating heart it may be difficult to place the sutures with the position precision required. In a beating heart procedure the surgeon can attempt to minimize the deleterious effects of the movement by using suspension or retraction techniques. However, it is impossible to isolate all movement of the vessel during an anastomosis procedure.

Methods that attempt to stabilize and isolate the artery from the movement of the beating heart can damage the vessel or cause myocardial injury (MI).

In addition to the problem of placing sutures accurately one must make an incision through the artery wall to open the artery. This too is a delicate procedure even on a still heart because the incision must be of a precise length. It is also critical to not penetrate the back wall or side wall of the vessel which will lead to complications. The placement of the initial incision is of paramount importance. The surgeon must pick a suitable location free from calcium deposits, fat and side branches.

Without cardioplegia, one must also provide blood flow to the heart muscle while the heart is beating, therefore, after the initial arteriotomy, the surgical field is very bloody and obscured.

Access to the heart vessels other than the LAD will be extremely difficult with minimally invasive hand suturing due to the anatomical location of the posterior wall of the heart.

While the art contains disclosures of several devices that are used to join blood vessels, these devices are primarily directed to an end-to-end anastomosis, which is inadequate for CABG procedures. Furthermore, the techniques disclosed in the prior art often require the vessels to be severely deformed during the procedure. The deformation may be required to fit the vessels together or to fit a vessel to an anchoring device. One cannot just slit the tissue and pull it through a ring to anchor it on a flange. Pulling or stretching the vessel walls produces a very unpleasant and unexpected result. Vessel walls are made of tissue fibers that run in the radial direction in one layer and the longitudinal direction in another layer. In addition the elasticity of the tissue fibers in the longitudinal direction is greater than those that run radially. Therefore, the tissue will not stretch as easily in the radial or circumferential direction and results in a narrowing or restriction when pulled or stretched in the prior art devices. Vessel walls also have a layer of smooth muscle cells that can spasm if treated harshly. Such manhandling will result in restrictions and stenotic junctions because the vessel walls will react poorly to being treated in such a rough manner and the stretching of the vessel wall will telegraph up the vessel wall due to the high radial stiffness of the vessel structure, causing restrictions and spasms in the vessel wall. The prior art fails to teach that the vessels are living tissue and must not be made to conform to rigid fitting-like shapes. Therefore, there is a need for an anastomotic technique that permits handling of blood vessels in a manner that is not likely to cause those blood vessels to react poorly.

to assure a proper flow area. In fact, the best results are obtained if the confluence area is actually oversized. The prior art junctions do not account for such flow characteristics and parameters and are thus deficient. Therefore, there is a need for an anastomotic technique which can establish proper flow characteristics and parameters and that accurately preserves blood vessel geometry, specifically the plural planar nature in which the junction occurs. Furthermore, most anastomoses are made between vessels that are not similar in size. It is therefore necessary to provide a means and method which allow for the accommodation and joining of dissimilarly sized vessels.

In addition, the inventors have found through post surgical follow-up that the supply vessels grow in diameter to accommodate their new role in providing oxygenated blood to the heart; therefore, there is a need to provide an oversized junction to accommodate any increase in the dimension of the graft vessel size. With a rigid ring that is a singular circular cross section of the graft, the fitting does not allow the vessel to provide this increase in flow as the vessels expand to meet the needs of the heart muscle. Still further, the inside lining of the vessel walls (intima) should make contact with each other to have proper healing. The walls of the vessels must come together with just the right amount of approximation to promote good healing. If the incised edges are too far apart scarring will occur causing restrictions. The walls cannot be compressed between two hard surfaces which will damage the vessels. The prior art teaches plumbing-like fittings clamped onto vascular structures. However, clamping and compressing the vessel walls too tightly will cause necrosis of the

region for vessel repair and healing, minimizing the distance between healthy endothelial cells on either side of the junction. This allows for the natural control processes which prevent platelet aggregation from extending beyond the area of injury. A more detailed description of the clot limiting process and the healing process can be found in various reference texts, such as "Coagulation: The Essentials", by Fischbach, David P and Fogdall, Richard P, published by Williams and Wilkins of Baltimore in 1981, the disclosure of Chapter 1 thereof being is incorporated herein by reference.

Still further, some vessels are located or sized in a manner that makes placing elements thereon difficult. In such a case, the fewer elements used to perform an anastomosis the better. Therefore, there is a need for a means and a method for performing an anastomosis that can be effected without the need of a hemostatic medium.

Many time when a CABG operation is undertaken, the patient has multiple clogged arteries. At the present time, the average number of grafts is 3.5 per operation. When multiple grafts are performed, there is sometimes the opportunity to use an existing or newly added supply vessel or conduit for more than one bypass graft. This is known as a jump graft, whereby the conduit, at the distal end thereof is terminated in a side-to-side anastomosis first, with an additional length of conduit left beyond the first junction. Then, an end of the conduit is terminated in an end-to-end junction. This saves time and resources and may be necessary if only short sections or a limited amount of host graft material is available.

At the present time, existing means and methods of performing an anastomosis do not permit the

efficiently, accurately and effectively form a proper anastomosis without stopping the patient's heart.

It is another object of the present invention to provide a means and method of performing an anastomosis without stopping the patient's heart in a minimally invasive manner..

It is another object of the present invention to provide a means and method of performing an anastomosis without stopping the patient's heart in a minimally invasive manner in which the blood vessels are joined together in such a way as to most efficiently promote healing.

It is another object of the present invention to provide a means and method of performing an anastomosis without stopping the patient's heart in a minimally invasive manner in which the blood vessels are joined together without squeezing, compressing or otherwise manhandling them.

It is another object of the present invention to provide a method and means to stabilize a vessel while performing an anastomotic procedure.

It is another object of the present invention to provide a means and method of performing an anastomosis without stopping the patient's heart in a minimally invasive manner in which the blood vessels are joined together to form a confluence area that accurately accounts for flow characteristics and flow parameters.

It is another object of the present invention to provide a means and method of performing an anastomosis without stopping the patient's heart in a minimally invasive manner in which blood vessels can be joined together in a side-to-side configuration.

It is another object of the present invention to provide a means and method of performing an anastomosis without stopping the patient's heart in a

It is another object of the present invention to provide an anastomotic means and method which can effect a junction without a hemostatic medium.

It is another object of the present invention to provide an anastomotic means and method which can be used in proximal junctions and in multiple anastomotic sites on the same vessel.

It is another object of the present invention to provide an anastomotic means and method which can be used in a means and a method for performing an anastomosis which will lend itself to efficient and cost-effective multiple by-pass techniques.

It is another object of the present invention to provide an anastomotic means and method which can be used in a means and a method for performing an anastomosis which will lend itself to efficient and cost-effective jump graft techniques.

It is another object of the present invention to provide an anastomotic means and method which is especially well suited for all types of blood vessel anastomosis procedures and techniques, such as, but not limited to, proximal, side-to-side, end-to-side, jump grafts as well as others that will occur to those skilled in the art based on the teaching of the present disclosure.

Summary of the Invention

When a patient shows symptoms of cardiac insufficiency which are not severe enough to warrant surgical intervention, the cardiologist is called on to clean out or open up the clogged arteries. One way to open the artery is to install an internal stent such as disclosed in US Patent Number 5,425,739. This stent is a prop that is most often configured like a cylindrical cage. The stent is delivered to the site over a balloon catheter. When

anastomoses. The device is also amenable to efficient manufacture.

In addition, these objects are accomplished by providing a flexible hemostatic medium to hold a malleable stiffening framework. The hemostatic media can be absorbable material or a fabric material that allows tissue ingrowth. The medium provides a supportive surface at the edges of the anastomosis for the natural vessel repair process.

Therefore, to address the need of hemostasis, the inventors have included a cuff material which can be made from a variety of materials to allow the anastomosis to perform in a leak free manner with the proper substrate for healing to occur. It is also anticipated that through more development, a special coating such as collagen coatings could be incorporated into the hemostatic medium to encourage tissue ingrowth, and to discourage excessive thrombosis. Such coatings and treatments will occur to those skilled in the art based on the teaching of the present disclosure. It is further anticipated that research will suggest that these media may be absorbable or made from non-woven fabrics, or combinations of both.

It is therefore shown that the use of a hemostatic medium is a novel approach to providing a complete minimally invasive anastomotic device which does not use excessive clamping forces.

Although a hemostatic material is shown in the preferred embodiment as a woven synthetic cuff, those skilled in the art will be taught by this disclosure to substitute other materials without departing from the scope of the present invention. The term "cuff" can be used to describe a form of hemostatic medium but is not meant to be limiting.

vessel and to adjust the shape of the cuff to accurately reflect the shape of the junction. A linkage connects the cuff engaging means to an operating element so a surgeon can easily operate the device. One of the anvils is received in a graft vessel and the other anvil is received in the artery to which the graft vessel is to be attached. The artery accommodated anvil includes a blood passage defining portion so blood can continue to flow through the artery during the procedure. Furthermore, the instrument stabilizes the vessel from the beating heart. The artery accommodated anvil is actually larger than the incision in the artery and is "button holed" into the artery via the incision. Once in place in the artery the surgeon can pull up on the vessel at the incision thereby moving the work area in conjunction with the vessel and isolating the work surface from the beating heart. This makes the cuff fastening accurate and precise. Also, it assures that the tool and the vessel are moving together to isolate the beating heart movement from the tool.

The device engages the cuff and not the blood vessel so shaping and movement occurs while applying only minimal and gentle pressure to the blood vessels. This permits the junction to be properly and fully customized without mishandling the blood vessels. The instrument also has guides for forming the fasteners o staples.

As can be understood from the foregoing, and as one skilled in the art will be able to understand from the teaching of the present disclosure, the means and method of the present invention can be applied to multiple grafts and to jump grafts thereby making such techniques possible and cost effective.

Figure 17 is a perspective view of an anastomosis formed using the single cuff form of the invention in a side-to-side configuration, those skilled in the art being able to understand what an end-to-side configuration will look like based on the teaching of the present disclosure.

Figure 18A shows a single cuff form of the invention just prior to drawing the ends of the two blood vessels together.

Figure 18B shows the single cuff form of the invention after the ends of the blood vessels have been drawn together.

Figure 19 is an exploded perspective view of one form of the invention in which two cuffs are used to join an artery with a graft.

Figure 20 is a perspective view of a section of the joined artery and graft using two cuffs.

Figure 21 is an elevational cross sectional view of the two cuff form of the invention in situ.

Figure 22 is a perspective view of the two cuff form of the invention in an anastomosis which joins a graft to an artery in an end-to-side configuration.

Figure 23 is a perspective view of the two cuff form of the invention in an anastomosis which joins a graft to an artery in a side-to-side configuration, with the graft being tied off by a suture.

Figure 24 is an elevational view of another form of the two cuff form of the invention showing how the two cuffs are held together whereby the graft and the artery are pulled together in healing abutment.

Figure 25 is an exploded perspective view of a tool used in performing the anastomosis according to the present invention.

Figure 25A is an exploded perspective view of a tool used in performing the anastomosis according to the present invention, with a cuff in place.

Figure 39 shows the tool used to join two cuffs together docked to one cuff and prior to joining that cuff to another cuff.

Figure 40 shows the tool docked to one cuff and joining that cuff to another cuff.

Figure 41 is a flow chart for the method of performing an anastomosis for a single cuff form of the invention with the vessels being joined in a side-to-side configuration.

Figure 42A is a flow chart for the method of performing an anastomosis for a double cuff form of the invention with the vessels being joined in a side-to-side configuration.

Figure 42B is a flow chart for the method of performing an anastomosis for a double cuff form of the invention with the vessels being joined in an end-to-side configuration.

Figure 43 shows a single cuff form of the invention which has omitted the hemostatic medium.

Figure 44 shows the continuously varying nature of the junction angle.

Figure 45 shows the double cuff form of the invention which has omitted the hemostatic medium.

Figure 46 shows how the means and method of the present invention can be applied to a multiple graft technique.

Detailed Description of the Preferred Embodiment of the Invention

Locating and performing the arteriotomy

By way of orientation, Figures 1 and 2 indicate the locating and performing of an arteriotomy. As is well understood to those skilled in the art, locating the position of an anastomosis is extremely important and extremely delicate. The location must be selected with extreme accuracy and precision. This

the case of a minimally invasive surgery, this precise placement may be nearly impossible.

As discussed above, some prior art anastomosis techniques have used a ring to join two vessels together. This technique is indicated in Figures 6-9 where ring 30 is placed between two end-to-end vessels in Figure 6 and rings 30' and 30'' are used with two end-to-side joined vessels in Figure 7. The rings serve as the means for holding the joined vessels together. However, the rings have several drawbacks, including evaginating the vessels, restricting the vessels so growth due to higher blood flow is restricted, and stretching the vessel which causes flattening of the vessel as indicated at portion 32 in Figure 8. As discussed above, the use of rings suggests that an anastomosis is being viewed as a plumbing connection between two conduits. As was also discussed above, this is simply not the case with actual blood vessels. As discussed above, if too much clamping is applied to the vessels, necrosis may occur. Unhealthy tissue may cause scarring and in fact may fail to heal. This situation is illustrated in Figure 9.

Therefore, the present invention is intended to permit the performance of an anastomosis in a minimally invasive manner yet to perform the procedure in an accurate manner and in a manner that promotes proper healing. The most effective healing will occur when the hemostatic medium is located on the outside of the blood vessel so any clots will form on the outside of the vessel. This basic concept is illustrated in Figure 10 which shows an anastomotic device AD comprising a hemostatic medium HM having a stent which includes means FM for fastening the stent to the vessel and which is located on the outside of one blood vessel B1 which

invention has each cuff individually mounted on a blood vessel by an instrument, and the two cuffed vessels brought together with the cuffs then coupled together.

Shown in Figures 11, 11A and 12 is a single cuff 40 embodying the present invention. The cuff is applied to a blood vessel and will couple that vessel to another vessel or to another cuff. The cuff can be applied to a blood vessel by an instrument while blood still flows through the vessel by using a stabilizing cuff application tool with a flow-through anvil. This enables anastomotic surgery to be performed without stopping the heart so the procedure can be carried out in a minimally invasive manner. The cuff also permits proper shaping of the junction without mishandling the blood vessels and places the two vessels in an orientation that promotes efficient healing.

Specifically, cuff 40 includes an oval shaped flexible body 42 having a long axis 44 and a short axis 46 with an oval shaped opening 48 defined therein by the cuff body central section 49. The preferred form of body 42 is a woven fabric suitable for use in surgery. A stiffening framework 50 of a retention means, such as a malleable material, is integrated into body 42 for retaining the cuff in a selected shape on a blood vessel. The preferred form of the retention means is sinuous and includes a plurality of malleable sections, such as section 52. In the present context, this element will be referred to as a retention means. However, as will occur to those skilled in the art based on the teaching of the present disclosure, depending on the context of the discussion, this element can also be referred to as a "stent" or a "stiffening band." One form of the material is a wire that is suitable for use in the

central hole 80 defined therein to engage a corresponding element on the instrument used to place the cuff. The means for shaping the cuff also includes a plurality of second docking extensions 82 having proximal ends 84 integral with alternate apexes of the stiffening framework 50 and a distal end 86 having an eyelet 88 with a central hole 90 for releasable connection to a corresponding element on the instrument used to place the cuff.

As will be discussed below, the docking extensions are engaged with the instrument, and once the cuff is anchored to a blood vessel, the instrument can be manipulated by the surgeon to shape opening 48 to the desired size and shape. once the desired size and shape have been established, the cuff and framework is released from the instrument.

As can be seen in Figure 11, the cuff has an hour glass shape in elevation, with body 42 having a first end section 92 and a second end section 94 of roughly the same outer dimension, with central section 49 having an outer dimension of less than those outer dimensions to define a waist section. Other forms of the single cuff are illustrated in Figures 13A-13F.

Use of the single cuff form of the invention is illustrated in Figures 14-18B. The tool for effecting the placement of the cuff and the coupling of the two vessels will be discussed below in connection with Figures 25 *et seq*. For present purposes, the results will be shown and discussed. As shown in Figure 14, after the graft vessel G and the artery A have been prepared, the cuff is placed on the artery A. The graft vessel is then moved into proximity of the cuff as shown in Figure 14 and joined to the cuff as shown in Figures 15 and 16.

variation in junction angle effects a properly shaped anastomosis for dissimilarly sized vessels. This angle will also vary at the heel and the toe depending on the appropriate angle of the graft vessel, as shown in Figure 44 at JA', JA'' respectively.

By way of reference, a single cuff side-to-side anastomosis is shown in Figure 17.

The double cuff form of the invention is illustrated in Figures 19-24. As can be seen (see, e.g., Figure 21), one cuff 40' is attached to a graft blood vessel G, and a second cuff 40'' is attached to the artery A. As can be seen in Figure 19, there is a spacing between the fastening means attaching the cuff to the vessel and the edge of the artery. This spacing is selected so the loose edge of the vessel can still be controlled, but the fastening means is not located too close to the edge of the vessel. Bringing the cuffs together in this manner does not mishandle the blood vessels and promotes efficient healing of the junction. A spacing of 1/2 mm to 1 mm is shown in Figure 19. However, this spacing is disclosed for the sake of completeness and is not to be taken as limiting.

Means for joining one cuff to the other in the double cuff form of the invention includes one unit 98 fixed to the graft (cuff) blood vessel G and one unit 99 fixed to the artery (cuff) A. As shown in Figure 19, a female element 100 is fixed to cuff 40' and a corresponding male element 102 is fixed to cuff 40''. Female element 100 includes an eyelet 104 that has an opening sized and shaped to snugly receive male element 106 mounted on element 102 to establish a friction fit between elements 100 and 102 that securely couples the two cuffs together. The preferred form of the cuff joining means includes

above-discussed male/female coupling shown in Figure 21.

An alternative form of the cuff joining means for the double cuff form of the invention is shown in Figure 24. This form of the cuff joining means includes rivets or staples 114 in place of the male and female elements discussed above. The rivets or staples are placed in bases 98 and 99 and hold the bases together in the manner discussed above for the male and female elements 104 and 106.

Instrument

As discussed above, the anastomosis technique of the present invention is intended to be performed in a minimally invasive manner. Therefore, the cuffs discussed above must be placed on blood vessels that are located inside a patient, with the artery carrying blood. As was also discussed above, the anastomosis technique of the present invention may involve extremely small blood vessels. Accordingly, the instrument used to effect the anastomosis must be very accurate and precise, yet will not mishandle the blood vessels during performance of the technique. The instrument will place a cuff on the artery while permitting blood to flow through that artery, and then will place a corresponding cuff on the graft blood vessel, or will attach the graft blood vessel to the single cuff mounted on the artery in the single cuff form of the invention. The instrument will then be used to shape the cuffs so the junction is the most efficient and will permit proper healing. All of this must be carried out in a minimally invasive manner.

The preferred form of the instrument used to mount a cuff to the artery in both forms of the invention and to mount the cuff to the artery and to the graft in the double cuff form of the invention is

A slot 194 is formed at the intersection of each leg and the center section, with slots 194 being sized and located to slidably receive rails 170. Sliding engagement between the rails and the slots permits the finger frame to move with respect to the handle frame longitudinally of the channel 190 as is indicated by the double-headed arrow 196, with handle frame 122 moving in direction 198 with respect to finger frame 126 to open the instrument anvils and moving in direction 200 with respect to the finger frame to close the instrument anvils as will be discussed below.

Each leg 186 of the finger frame 126 further includes an ear, such as ear 202 on a distal end thereof to which a guide pin, such as guide pin 204, is fixed to extend past the handle frame leg adjacent thereto.

Instrument 120 further includes two pivot pins 206 and 208 accommodated in the aligned bores 164 and 166. Each of the driver arms 130 and 132 has a pivot pin receiving hole 210 and 212 respectively defined in the proximal end of arms 214 and 216 respectively. A crescent-shaped driver element 218 and 220 is located on the distal end of each arm 214 and 216 respectively with a cam slot 222 and 226 being defined in the arms 214 and 216 respectively.

The arms are pivotally attached to the handle frame by the pins 206 and 208 to move in directions 226 and 228 as indicated by double-headed arrow 230 when finger handle 126 moves directions 198 and 200 respectively to open and close the driver heads 218 and 220. Slots 222 and 226 slidably receive guide pins 204 to effect this opening and closing movement. Since the driver arms are fixed at an angle to handle frame 122 by pivot pins 206 and 208 and guide pins 204 move longitudinally with respect to the handle

anvil in direction 262 and threaded movement in the opposite direction moves the graft anvil in direction 260 whereby the location of the graft anvil head 244 with respect to the driver elements 218, 220 can be adjusted and set. The purpose of this movement will be understood from the discussion in this disclosure.

A groove in knob 247 engages lip 176 of handle 120. Since knob 247 remains stationary the anvil moves up or down to bend or cinch the fasteners 62. Body 240 includes a first portion 248 and a second portion 250 that is angled with respect to the first portion 248. Graft anvil head 244 has a proximal end thereof fixed to portion 250 to extend transverse to longitudinal centerline 252 of the body 240. The length of body 240 as measured between its proximal and distal ends is greater than the length of the handle frame as measured along its longitudinal centerline 252 between the shoulder 176 and distal end 256 whereby graft anvil head 244 is spaced from distal end 256 when the graft anvil 134 is mounted on the handle frame. Arm 248 is also long enough so that graft anvil head 244 is also spaced from driver heads 218 and 220 when the graft anvil is in place on the handle frame. Alignment pins 246 are received through anvil slots 148 and 150 and are slidably accommodated in slots 154 so the graft anvil is securely and movably affixed to the handle frame.

Artery anvil 136 includes a body 270 having a threaded portion 272 on a proximal end thereof and an artery anvil head 274 on a distal end thereof. Alignment pins 276 are located on the body to be received through alignment slots 152 and slidably accommodated in slots 154 on the handle frame. When the artery anvil is attached to the handle frame, threaded portion 272 extends through channel 178 and is threadably received by knob 247 to attach the

of the finger frame 122 and as the artery anvil is moved in direction 260 by operation of the knob 247 on threaded portion 272.

Driver heads 218, 220 include docking pins 294 which releasably engage holes 80 and 90 of the docking pins 70 and 82 on the cuff to control the shape of the cuff. The friction fit between pins 294 and the pins 70 and 82 is great enough to permit the cuff to be pulled and shaped by movement of the driver heads, but low enough so the pins 294 can be pulled out of the docking elements without pulling the cuff off of the blood vessel. Alternatively, pins 294 could be retracted through a flexible shaft connected up to the handle. Pulling the driver heads outwardly in direction 226 will enlarge the junction and will change its shape from oblong toward circular. Therefore, a surgeon can shape the junction in the manner that is most efficient to healing and to defining an effective anastomosis.

An assembled instrument is shown in Figure 26 with an artery anvil being inserted through an incision I in an artery A and a cuff 40 on the driver elements. As can be seen, once the incision is made, the artery anvil head is button holed into the artery via the incision. The anvil head is actually larger than the incision in the artery but can be angled through the incision into position as shown in Figure 26. The knob 247 is operated to draw the anvil head and vessel surface at the incision up toward heads 218, 220. This action also isolates the working area from motion associated with the beating heart. As indicated in Figure 27, after the head supported cuff contacts the outside of the artery, driver heads 218, 220 are operated to force the edges 232 against the waist 49 and against the surfaces 236 and 238, and the knob 247 is further operated to draw the anvil

fasteners in the artery. This is illustrated in Figure 29 for a single cuff embodiment. Turning section 296 is used to turn the tissue retention pins to either attach a single cuff to the blood vessel or to attach a separate cuff to the blood vessel. Once the cuff is attached to the graft (for the single cuff embodiment), or the cuff on the graft is attached to the cuff on the artery (for the double cuff embodiment) by attaching the coupling elements 106 and 104 (for the double cuff form) or the bridges 110 are manipulated to bring the inside edges 26 and 26' of the vessels together, the driver heads 218, 220 are manipulated to enlarge the graft incision to permit the graft anvil head to be withdrawn from the graft vessel via the end of that vessel. The driver heads can then be further manipulated to size and shape the junction, and then manipulated to remove the docking pins 70 and 82 from the anvil pins 294 to release the cuff or cuffs from the instrument. The garrot suture is cut and the graft anvil is removed from the graft. The graft blood vessel is then tied off and the anastomosis is complete.

Instrument for mounting a cuff on the graft artery

Shown in Figures 30-34 is one form of an instrument used to mount a cuff on a graft artery. An alternative form of the instrument is shown in Figures 35-37.

As shown in Figure 30, a graft G is prepared by defining an incision IG therein. The graft has been removed and is being prepared and cuffed outside of the patient. An instrument 300 is shown in Figure 31 and includes tongs 302 and 304 having cuff-engaging ends 302' and 304' respectively, and handles 302'' and 304'' respectively which are gripped by the surgeon. A pivot 306 is located at the intersection

322 and 324 downwardly until turning areas 343 and 345 engage the ends of fasteners 66. Further movement of the elements 322, 324, turns fasteners around to attach the cuff to the graft vessel in the manner of a staple. Once the cuff is secured to the vessel, the anvil is released, and the cuff and attached vessel removed from the instrument 300. As will be understood from the above discussion, the fasteners 66 are evenly turned by the anvil to evenly mount the cuff to the graft. The cuffed graft can then be laid aside until it is needed.

An alternative form of an instrument used to mount a cuff on a graft is shown in Figures 35-37. The graft is prepared in the manner discussed above.

End cuff attaching tool 350 includes a housing 352 having a forming cavity 354 defined therein to extend from end wall 356 adjacent to edge forming elements 358 and 360. Housing 352 is slidably mounted on plate 362 by a track 363 to be moved by hand pressure in directions 363' and 363''. Housing 364 is mounted on plate 362 and slidably receives a pushrod 366. Pushrod 366 has a link 368 attached at one end thereof by a pivot pin 370. Pushrod 366 can be operated by hand to move in directions 372 and 374 as indicated by double-headed arrow 376.

A tilt table 380 is pivotally attached to the plate 362 by pivot pins, such as pin 382, and is pivotally attached to the link 368 by pin 384. As can be seen in Figure 35, movement of the pushrod in direction 374 tilts the table in direction 386 about pin 382, and vice versa for pushrod movement in direction 372. The table moves from the position shown in Figure 35A to the position shown in Figure 35C under the influence of this pushrod movement.

A vessel receiving element 390 is mounted on one end of the plate 362 to extend upwardly and outwardly

in direction 363' and, table 380 moved opposite to direction 386. The cuffed-graft can then be removed from the shaft 390. The J-shape of fasteners 66' prevents the graft vessel from becoming damaged from otherwise protruding pins from the cuff as the tilt-table is being rotated. The variation in shape of the fasteners thus protects the graft vessel.

As before, once the graft vessel is cuffed, it can be set aside until the artery is cuffed.

Instrument for coupling one cuff to another

Shown in Figures 38-40 is an instrument that can be used to couple one cuff to another in the double-cuff form of the invention. As shown in Figure 38, instrument 450 is releasably attached to a vessel-mounted cuff, and is then operated to attach that cuff to another vessel-mounted cuff. One cuff can be attached to an artery using the instrument shown in Figure 25 (using elements 130, 132 and 136) while a cuff can be attached to a graft using the instrument shown in either Figure 31 or Figure 35 in an end-to-side anastomosis, or using the instrument shown in Figure 25 twice (using elements 130, 132 and 136 to attach a cuff to an artery and using element 134 to attach a cuff to a graft) in a side-to-side anastomosis.

The two cuffs are attached together using instrument 450 shown in Figure 38. Instrument 450 includes a handle 452 having a hand-grip 454 on one end thereof. A trigger housing 456 is mounted adjacent to the hand grip. An anchor element 458 is also mounted on the handle adjacent to the hand grip. A cuff engaging section 460 is mounted on the other end of the handle and includes a base 462 having a forward end 464 and an aft end 466. Cuff engaging C-shaped hooks 468 are pivotally mounted on the base section by pivot bars, such as bar 470 extending

through guides 508. Levers 506 are pivotally mounted on the base section by pins 510 to move in direction 512 when the trigger housing is moved in direction 514. The pivot pins 510 are fixed to rod 470 to rotate that rod in direction 512 with the levers. Hooks 476 and 478 are fixed to the rod 470 for rotation therewith, and rotation of the levers in direction 512 rotates the rod 470 in direction 516. Rotation of the hooks 476 and 478 in direction 516 moves those hooks from the Figure 38 position to the cuff engaging position shown in Figure 40. Rod 470 is also spring biased by a torsion spring, so when the trigger housing is released, that rod will rotate to release hooks 476 and 478 back into the Figure 38 position.

After the tool is mounted to a cuff, that cuff is attached to the other cuff. The cuff and tool are moved adjacent to the other cuff, as shown in Figure 39, and the two cuffs are brought together and coupled as above described.

Method

Figures 41, 42A and 42B represent the method of using the above-described instrument in performing an anastomosis according to the teaching of the present invention.

The following steps are used to effect the anastomosis of the present invention in the single cuff method.

The location of the anastomosis is determined.

The graft is pulled onto the graft anvil.

The graft is garroted to the graft anvil.

The graft and graft anvil are set aside.

Perform arteriotomy.

Button-hole artery anvil into interior lumen of the artery.

Dock the artery anvil to the instrument.

is shown in Figure 43 as tissue pins attached to an external malleable stent S. Tissue is shown as T.

It is further possible at that point to join the two stents with materials that are flexible but which still hold the edges in approximation creating a living hinge between the two stents. The junction SJ will thus be a living hinge about which the two vessels can pivot or move. Figure 43 shows a single cuff design with only one bridge being shown for the sake of clarity of disclosure, it being understood that other bridges, as discussed above, are also included in the Figure 43 embodiment. A double cuff design is shown in Figure 45, with only one coupling element being shown.

Although this invention has been disclosed and illustrated to show the anastomosis of small distal grafts, there are other surgical procedures that will benefit from this type of improvement as will occur to those skilled in the art based on the teaching of this disclosure. For example, a proximal graft attachment to aortic supply, an anastomosis of other luminal structures such as, but not limited to, Fallopian tubes urethra, ureter, bile ducts, etc. can also be performed using the means and method disclosed herein.

Figure 46 shows the use of the present means and method as applied to multiple grafts. As above discussed, where an existing blood supply conduit, such as the IMA, is not available to use, an artificial supply vessel must be grafted. Usually another vessel such as the saphenous vein is harvested from the patient's leg. At this point, the graft must be attached to a supply. This is usually the aorta AA. In the area above the aortic valve, a proximal anastomosis P is performed using the techniques discussed above to attach the new supply

CLAIMS

1. An anastomotic device comprising:

A) a first malleable mounting structure for mounting on a first vessel;

B) a second malleable mounting structure for mounting on a second vessel;

C) fastener means for fastening said first mounting structure to said second mounting structure; and

D) means in each mounting structure for maintaining the mounting structure associated therewith in a selected shape so a desired flow area and shape can be established at the junction of said first and second vessels.

2. For use in connecting a first vessel to a second vessel, each vessel having an inside edge surface extending radially of a wall of the vessel, an anastomotic device comprising: means for placing the inside edge surface of the first vessel in abutting, healing contact with the inside edge surface of the second vessel so the vessels heal together at the inside edge surfaces of the vessels, a stiffening framework said stiffening framework being formed of deformable material which causes said stiffening framework to remain in a second configuration after being deformed from a first configuration, means on said stiffening framework for attaching said stiffening framework to the outside surfaces of both the first and second vessels, said stiffening framework holding the inside edge surfaces of the first and second vessels in a first orientation when the stiffening framework is in one configuration and causing the inside edge surfaces of the first and second vessels to be in healing contact with each other when the stiffening framework is in a second configuration.

10. The anastomotic device defined in Claim 9 wherein said anvil includes a curved surface for turning staples.

11. The anastomotic device defined in Claim 2 wherein said first and second vessels are in side-to-side contact with each other.

12. An anastomotic device comprising: a mounting structure for mounting on the outside surface of a first vessel adjacent to an incision and on the outside surface of a second vessel adjacent to an incision in the second vessel, said mounting structure being formed of deformable material that causes it to retain a second configuration after being deformed from a first configuration, the outside surfaces being located outside the vessels after the incisions have healed.

13. The anastomotic device defined in Claim 12 further including means connecting said mounting structure to said vessels in position so that an inside edge of said first vessel immediately adjacent to the incision in said first vessel is in healing contact with an inside edge of said second vessel immediately adjacent to the incision in said second vessel.

14. The anastomotic device defined in Claim 1 wherein said means in each mounting structure for maintaining the mounting structure in a selected shape includes a sinuous stiffening element.

15. The anastomotic device defined in Claim I wherein each mounting structure is mounted adjacent to an incision in the vessel associated therewith and

C) a driver means attached to another end of said linkage to be operated by said linkage for fastening a mounting structure to a vessel.

21. The device defined in Claim 20 further including an anvil having a body sized to be received in said channel and a head which is inserted into a vessel.

22. The device defined in Claim 21 wherein said head includes a means for defining a blood flow passage.

23. The device defined in Claim 22 wherein said head further includes means for turning staples.

24. The device defined in Claim 23 wherein said driver means includes a staple engaging surface.

25. The device defined in Claim 24 wherein said mounting structure engaging surface is V-shaped in cross sectional shape.

26. The device defined in Claim 23 wherein said driver means includes an arcuate vessel engaging surface.

27. The device defined in Claim 21 further including a second anvil.

28. The device defined in Claim 27 wherein said second anvil includes a portion which is received inside a vessel via an end of said vessel.

29. The device defined in Claim 1 wherein said mounting structures are hourglass-shaped.

35. An anastomotic device comprising:
A) a stent located on a vessel to be joined to another vessel, said stent including a framework formed of deformable material that causes said framework to retain a second configuration after it has been deformed from a first configuration;
B) means for deforming said stent; and
C) vessel attaching means on said stent for attaching said stent to the outside surface of the vessel, and to position the inside surface of the vessel adjacent to the inside surface of another vessel.

36. The method defined in Claim 34 wherein the step of shaping the fastened mounting structures includes defining a flow area which exceeds a cross sectional area defined by one of the vessels prior to said attaching step.

37. The method defined in Claim 34 further including a step of positioning the vessels in side-to-side orientation prior to said attaching step.

38. The method defined in Claim 34 further including a step of positioning the vessels in end-to-side orientation prior to said attaching step.

39. The anastomotic device defined in Claim 2 wherein each of said first and second mounting structures includes a flexible body, and means for attaching said body to a vessel.

40. The method defined in Claim 34 further including a step of maintaining blood flow through one of the vessels.

D) shaping said mounting structure to define a desired flow area and shape for the junction of the two vessels.

45. A method of performing an anastomosis comprising: maintaining blood flow in a vessel; defining an incision in the vessel; fastening a stent on the outside of the vessel; and shaping the stent.

46. The method defined in Claim 45 further including stabilizing the vessel during the step of fastening the stent.

47. The method defined in Claim 41 further including a step of drawing the vessels together.

48. The method defined in Claim 41 further including a step of stabilizing the first vessel.

49. The method defined in Claim 41 further including a step of positioning the inside edges of each vessel in abutting contact with each other.

50. The method defined in Claim 34 further including shaping the fastened mounting structures to define a desired flow area between the first and second vessels.

51. An anastomotic device comprising:
A) a hemostatic medium;
B) a stent located on the outside of one vessel which is to be joined to another vessel; and
C) means for bringing vessel walls of said one vessel into intimate approximation with other vessel walls of said another vessel.

59. The anastomotic device defined in Claim 56 wherein the junction formed between the two vessels is sinuous in shape.

60. The anastomotic device defined in Claim 52 further including means for placing said retention means in said vessel.

61. The anastomotic device defined in Claim 60 wherein said means for placing said retention means includes an anvil.

62. The anastomotic device defined in Claim 61 wherein said anvil includes a curved surface for turning said staples.

63. The anastomotic device defined in Claim 2 wherein said means in each mounting structure for maintaining the mounting structure in a selected shape includes a sinuous stiffening element.

64. The anastomotic device defined in Claim 2 wherein each mounting structure is mounted adjacent to an incision in the vessel associated therewith and said flow area is larger than the area of one of said vessels whereby said one vessel is enlarged when said mounting structures are fastened together.

65. The anastomotic device defined in Claim 2 further including a blood flow passage defining means in one of said vessels for maintaining blood flow while said mounting structures are being mounted to said vessels and fastened to each other.

66. A device for performing an anastomosis comprising:

staggered relationship with respect to pins on the second frame to compress tissue located between pins on opposing rings.

72. The anastomotic device defined in Claim 70 further including a docking system for connecting the stiffening framework on the first vessel to the stiffening framework on the second vessel for producing a compliant joint.

73. The anastomotic device defined in Claim 56 further including means for aligning and attaching said frames.

74. The anastomotic device defined in Claim 70 further including tissue fastening means which includes pins which are arranged with respect to each other to force tissue interposed between pins between the frames.

5. The anastomotic device defined in Claim 1 wherein each of said first and second mounting structures includes a flexible body, and means for attaching said body to a vessel.

6. The anastomotic device defined in Claim 5 wherein said means for attaching said body to a vessel includes retention means.

7. The anastomotic device defined in Claim 6 further including means for placing said retention means in said vessel.

8. The anastomotic device defined in Claim 7 wherein said means for placing said retention means includes an anvil.

9. The anastomotic device defined in Claim 8 wherein said anvil includes a curved surface for turning staples.

10. The anastomotic device defined in Claim 1 wherein said means in each mounting structure for maintaining the mounting structure in a selected shape includes a sinuous stiffening element.

11. The anastomotic device defined in Claim 1 wherein each mounting structure is mounted adjacent to an incision in the vessel associated therewith and said flow area is larger than the area of one of said vessels whereby said one vessel is enlarged when said mounting structures are fastened together.

12. The anastomotic device defined in Claim 11 wherein said means in each mounting structure for maintaining the mounting structure in a selected shape enlarges the incision in one vessel and decreases the size of the incision in the other vessel.

configuration. the outside surfaces being located outside the vessels after the incisions have healed.

16. The anastomotic device defined in Claim 15 further including means connecting said mounting structure to said vessels in position so that an inside edge of said first vessel immediately adjacent to the incision in said first vessel is in healing contact with an inside edge of said second vessel immediately adjacent to the incision in said second vessel.

17. The anastomotic device defined in Claim 14 wherein said first and second vessels are in side-to-side contact with each other.

18. The anastomotic device defined in Claim 14 wherein said first and second vessels are in end-to-side contact with each other.

19. The anastomotic device defined in Claim 14 further including means for defining a blood flow passage and located in one of said vessels for maintaining blood flow in the one vessel while the inside edge of the one vessel is being placed in abutting contact with the inside edge of the second vessel.

20. The anastomotic device defined in Claim 14 wherein said stiffening framework includes a flexible body. and means for attaching said body to a vessel.

21. The anastomotic device defined in Claim 20 wherein said means for attaching said body to a vessel includes retention means.

22. The anastomotic device defined in Claim 21 further including means for placing said retention means in said vessel.

23. The anastomotic device defined in Claim 22 wherein said means for placing said retention means includes an anvil.

30. An anastomotic device comprising:

A) a first malleable frame mounted on an outside surface of a first vessel;

B) a second malleable frame mounted on an outside surface of a second vessel;

C) fastener means for fastening said first malleable frame to said second malleable frame; and

D) means in each malleable frame for maintaining the malleable frame associated therewith in a selected shape so a desired flow area and shape can be established at the junction of said first and second vessels.

31. The anastomotic device defined in Claim 30 further including a living hinge located at a junction formed between the first and second vessels.

32. The anastomotic device defined in Claim 30 wherein said fastener means include tissue retention pins that are staggered with respect to each other.

33. The anastomotic device defined in Claim 30 wherein the junction formed between the two vessels is sinuous in shape.

34. The anastomotic device defined in Claim 30 further including means for aligning and attaching said frames.

35. An anastomotic device comprising: means for placing an inside edge surface of an incision in a first vessel in abutting contact with an inside surface of an incision in a second vessel so the vessels heal together at the inside edge surfaces of the vessels, and a stiffening framework located on the

42. The device defined in Claim 41 wherein said body has a channel defined therein, said device further comprising an anvil having a body sized to be received in said channel and a head proportioned for insertion into a vessel.

43. The device defined in Claim 42 wherein said head includes a blood flow passage.

44. The device defined in Claim 43 wherein said head further comprises structure for turning staples.

45. The device defined in Claim 44 wherein said driver includes a staple engaging surface.

46. The device defined in Claim 45 wherein said engaging surf ace is V-shaped in cross sectional shape.

47. The device defined in Claim 44 wherein said driver includes an arcuate vessel engaging surface.

48. The device defined in claim 42 further comprising a second anvil to be used in place of the first anvil, said second anvil having a body sized to be received in said channel and a head proportioned for insertion into a vessel via an end of said vessel.

49. A device for performing an anastomosis comprising:

A) a member for supporting a malleable stent for securement to a vessel;

B) an anvil for controlling tissue fastening elements of a stent supported by the member to secure the stent to a vessel; and

edge of the first vessel adjacent to the incision therein is spaced from an inner edge of the first mounting structure;

D) fastening the first mounting structure to the first vessel;

E) positioning a second mounting structure on the second vessel adjacent to the incision in the second vessel so that an inner edge of the second vessel adjacent to the incision therein is spaced from an inner edge of the second mounting structure;

F) fastening the second mounting structure to the second vessel; and

G) attaching the first and second mounting structures together.

57. The method defined in Claim 56 wherein the step of attaching the first and second mounting structures together includes positioning the inner edges of the vessels in abutting contact with each other after said attaching steps.

58. The method defined in Claim 56 further comprising a step of shaping the fastened mounting structures to define a flow area which exceeds a cross sectional area defined by one of the vessels prior to said attaching step.

59. The method defined in Claim 56 further comprising a step of positioning the vessels in side-to-side orientation prior to said attaching step.

60. The method defined in Claim 56 further comprising a step of positioning the vessels in end-to-side orientation prior to said attaching step.

C) fastening a mounting structure to each vessel adjacent to each incision; and

D) shaping said mounting structure to define a desired flow area and shape for the junction of the two vessels.

65. A method of performing an anastomosis comprising: maintaining blood flow in a vessel; defining an incision in the vessel; fastening a stent on the outside of the vessel; and shaping the stent.

66. The method defined in Claim 65 further comprising stabilizing the vessel during the step of fastening the stent.

67. The method defined in Claim 61 further comprising a step of drawing the vessels together.

68. The method defined in Claim 61 further comprising a step of stabilizing the first vessel.

69. The method defined in Claim 61 further comprising a step of positioning the inside edges of each vessel in abutting contact with each other.

70. The method defined in Claim 56 further comprising a step of shaping the fastened mounting structures to define a desired flow area between the first and second vessels.

71. The method defined in Claim 65 further comprising steps of performing multiple grafts.

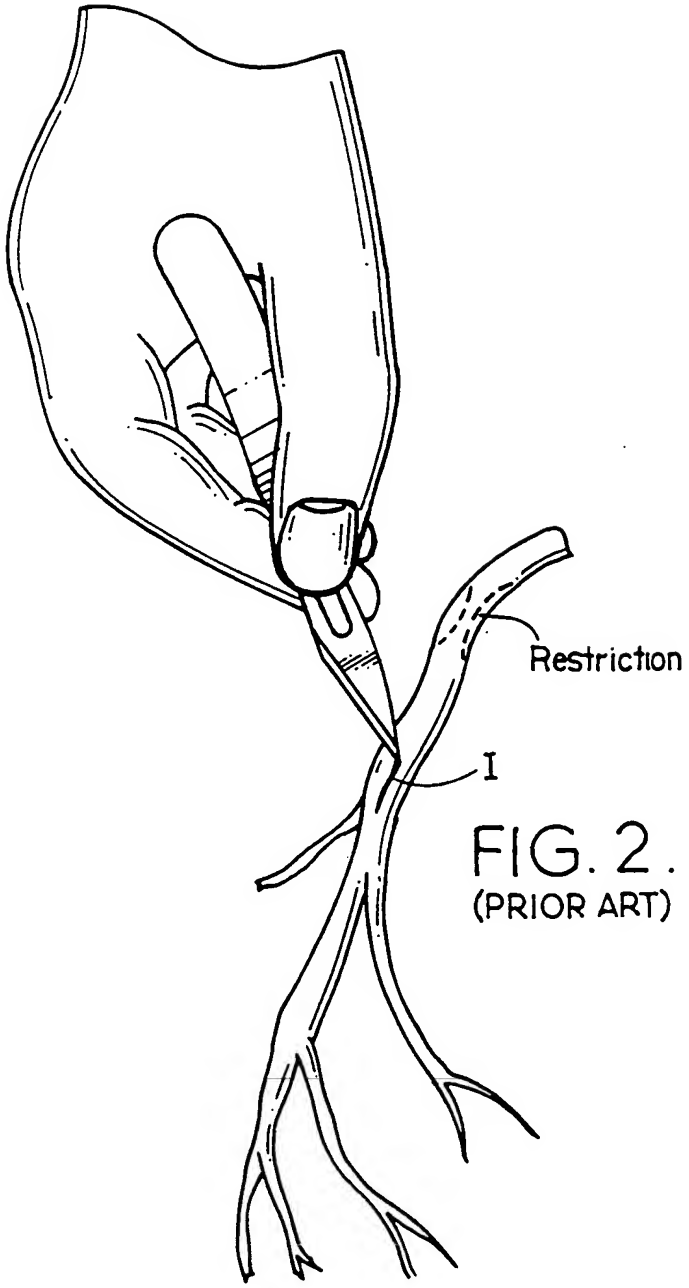


FIG. 2.
(PRIOR ART)

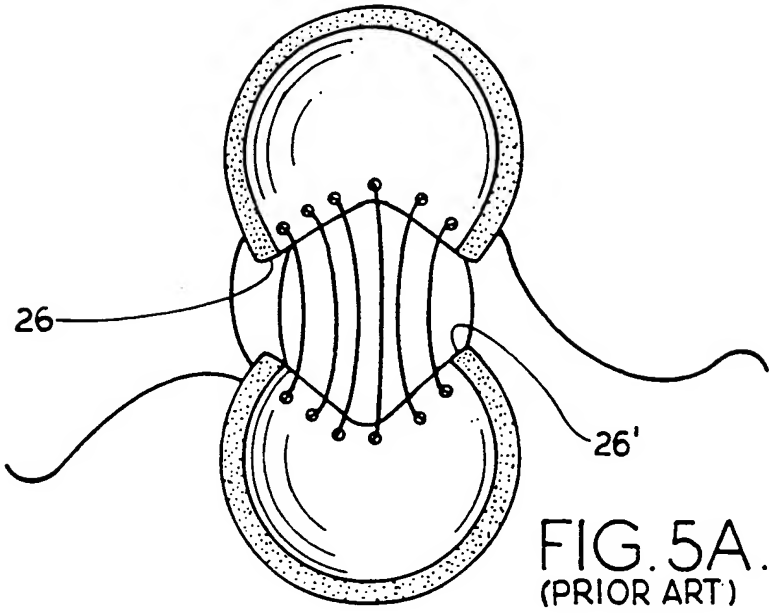


FIG. 5A.
(PRIOR ART)

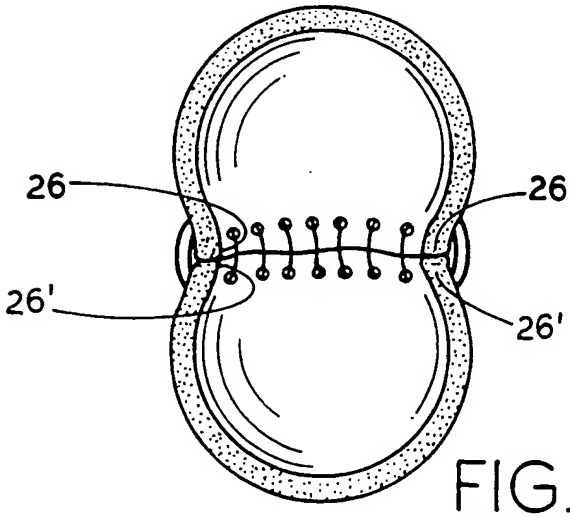


FIG. 5B.
(PRIOR ART)

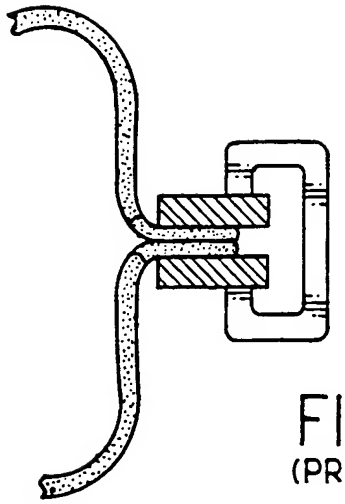


FIG. 9.
(PRIOR ART)

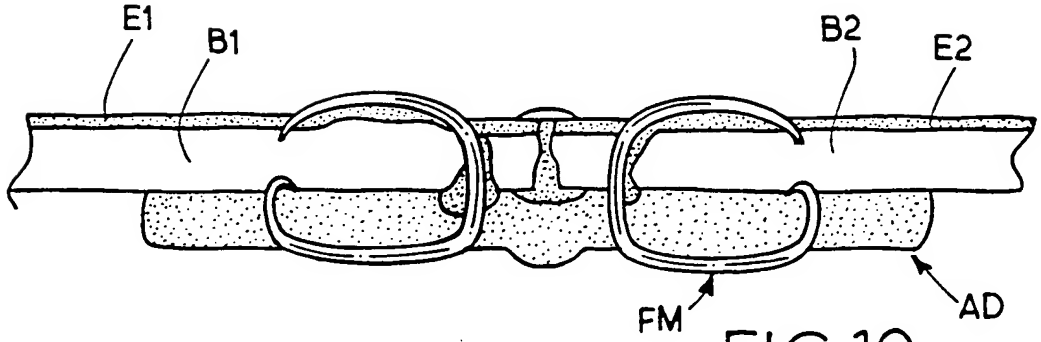


FIG. 10.

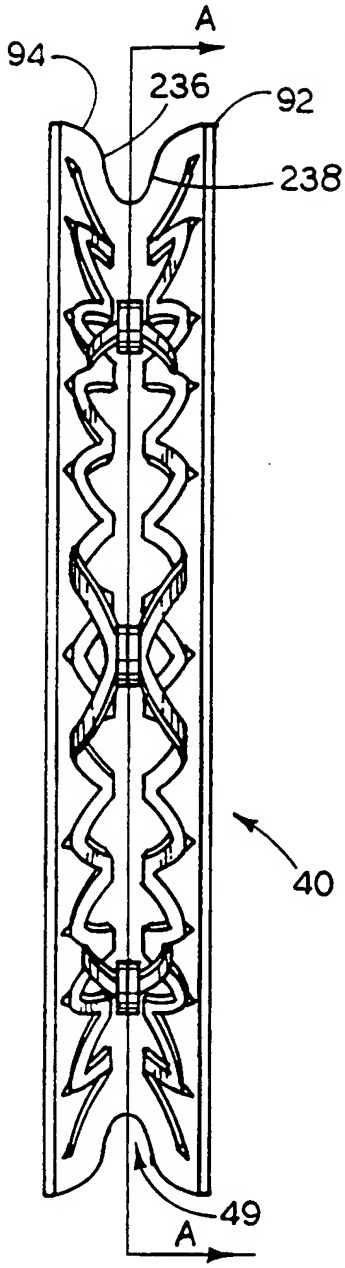


FIG.11.

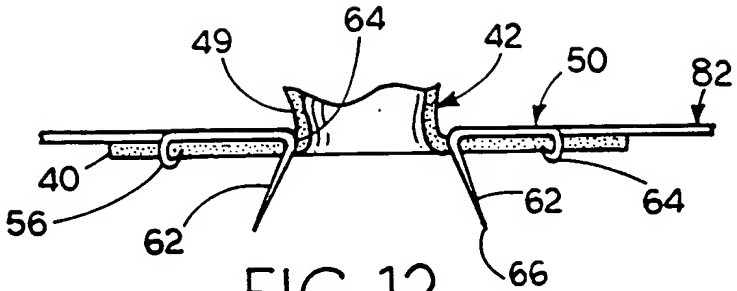


FIG.12.
SECTION B-B

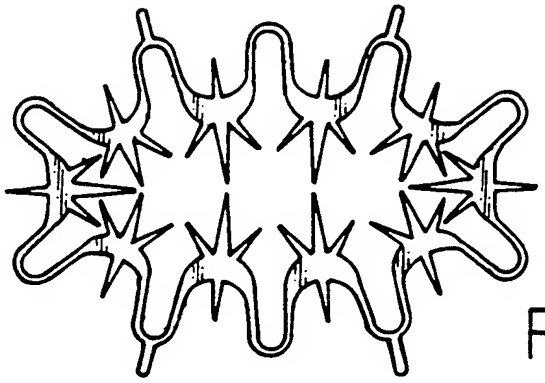


FIG. 13D.

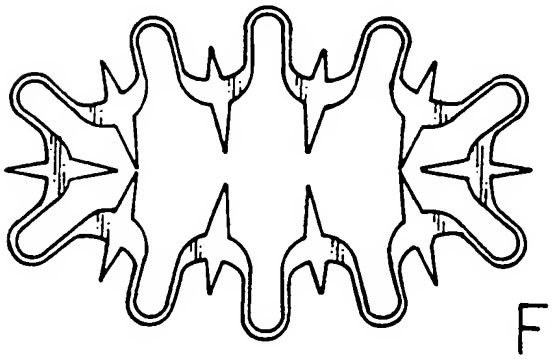


FIG. 13E.

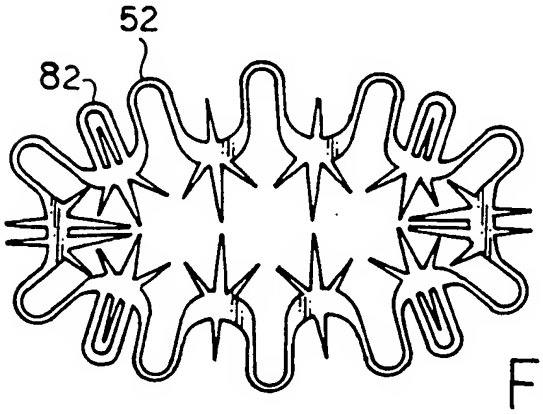


FIG. 13F.

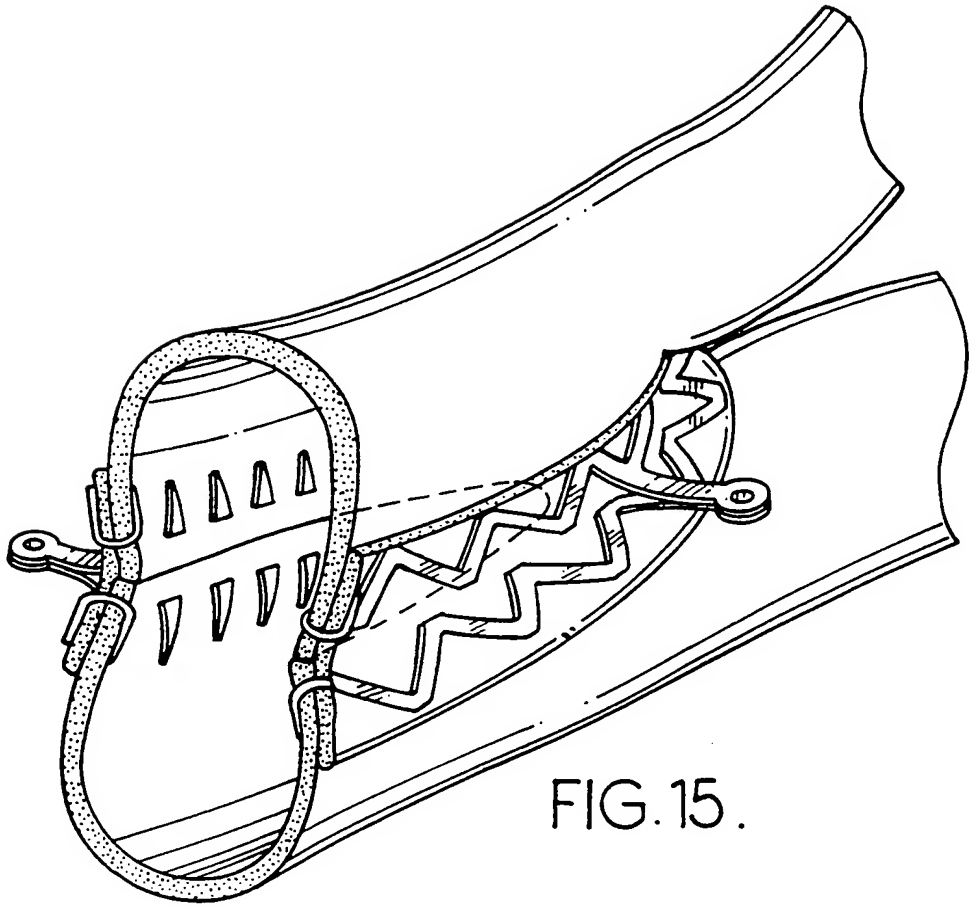


FIG. 15.

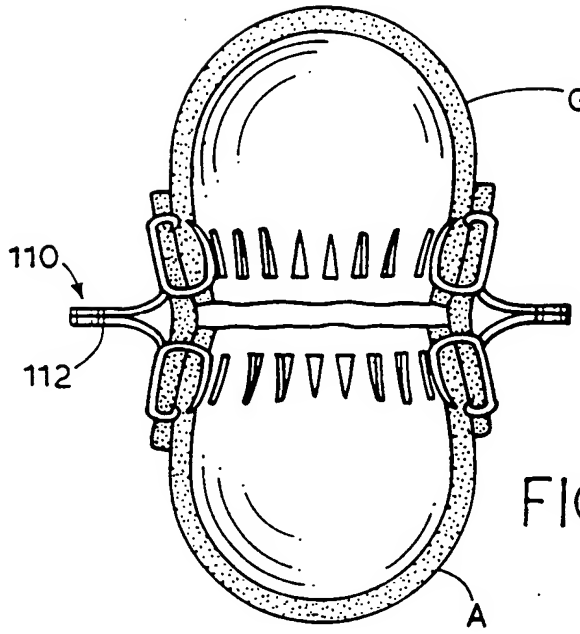


FIG. 18A.

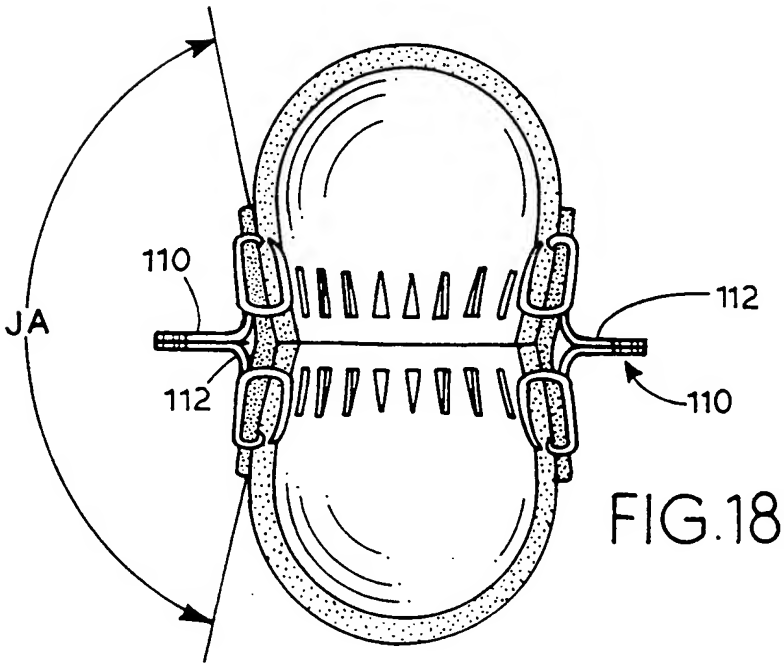
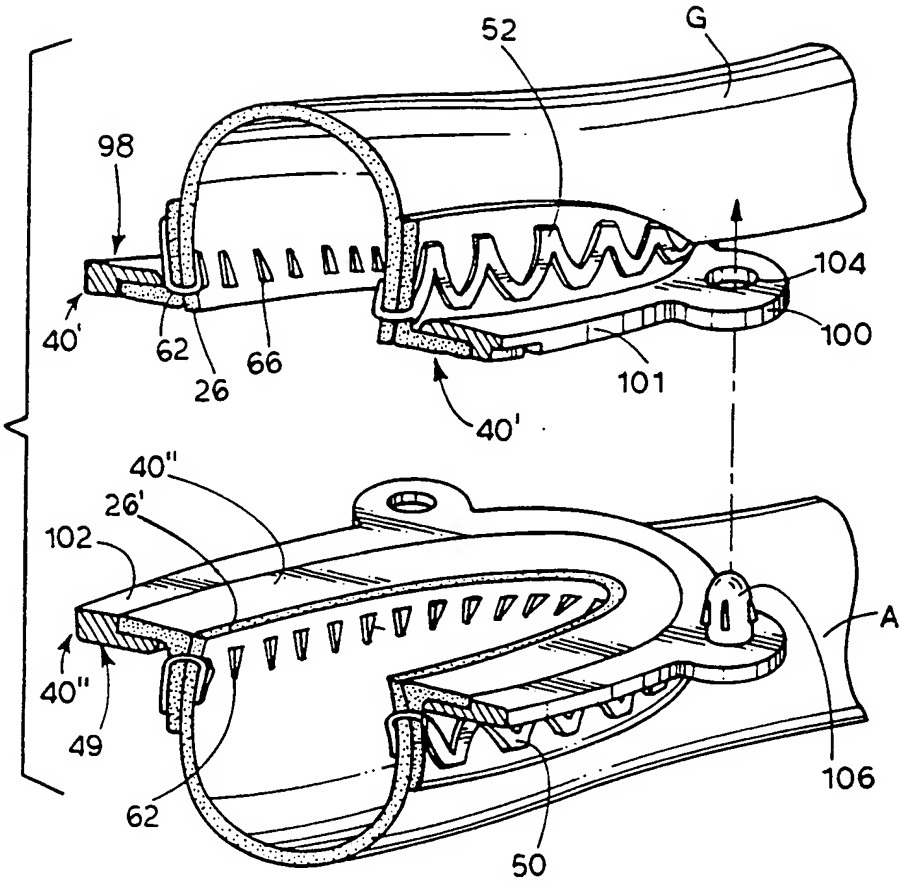


FIG. 18B.

FIG.19.



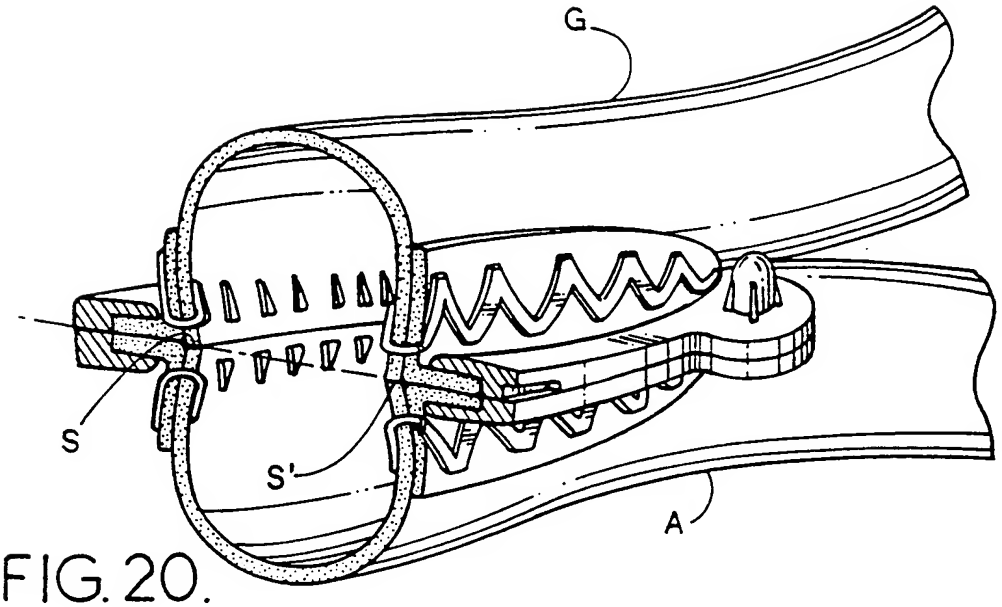


FIG. 20.

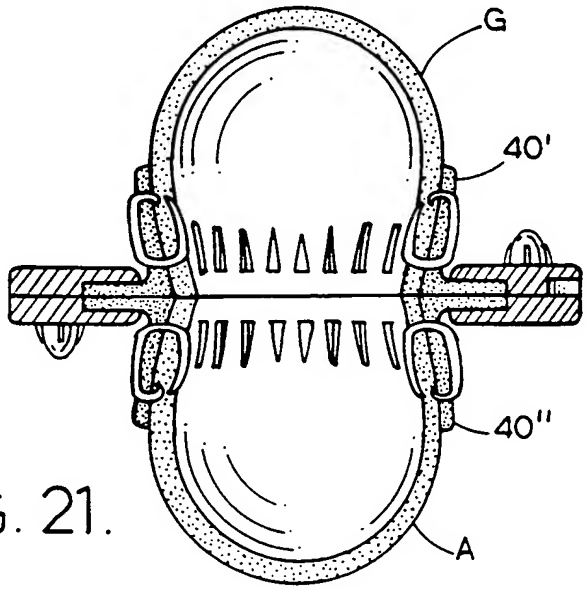


FIG. 21.

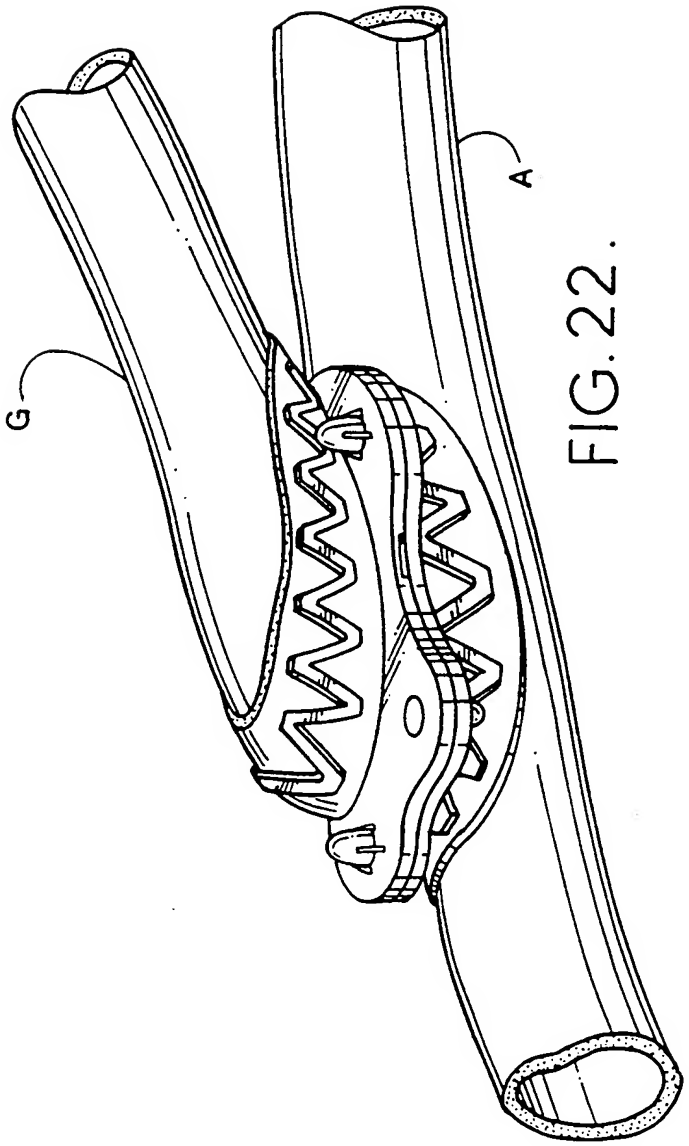
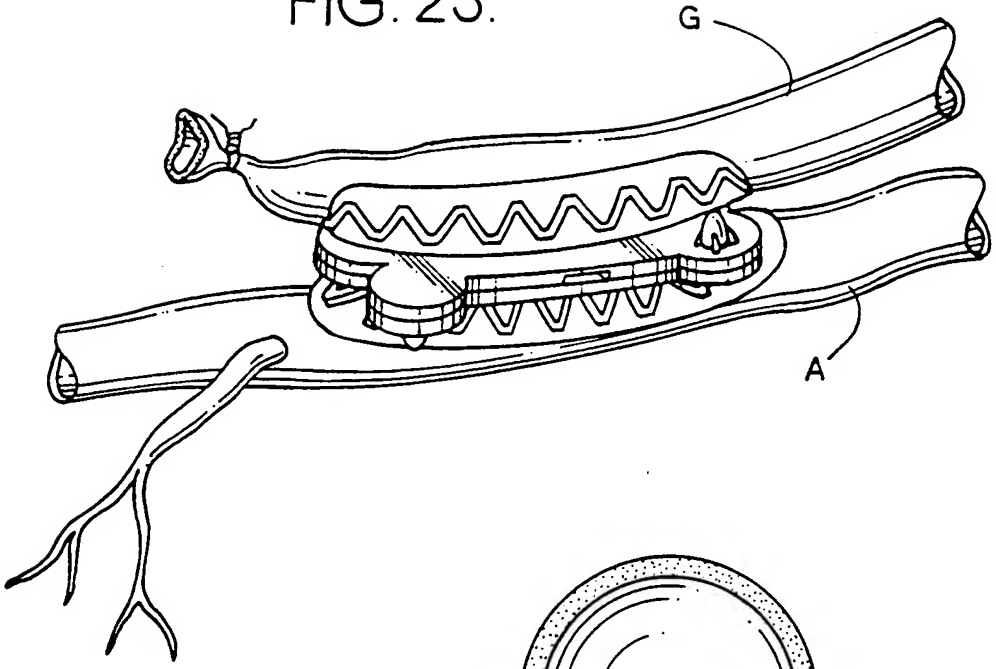


FIG. 22.

FIG. 23.



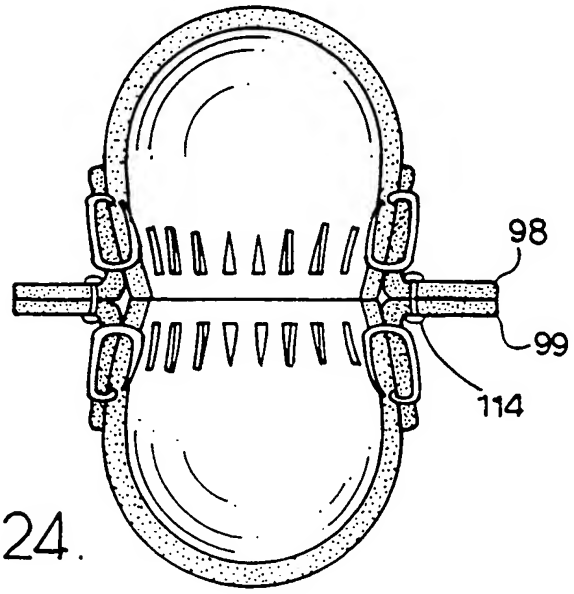


FIG. 24.

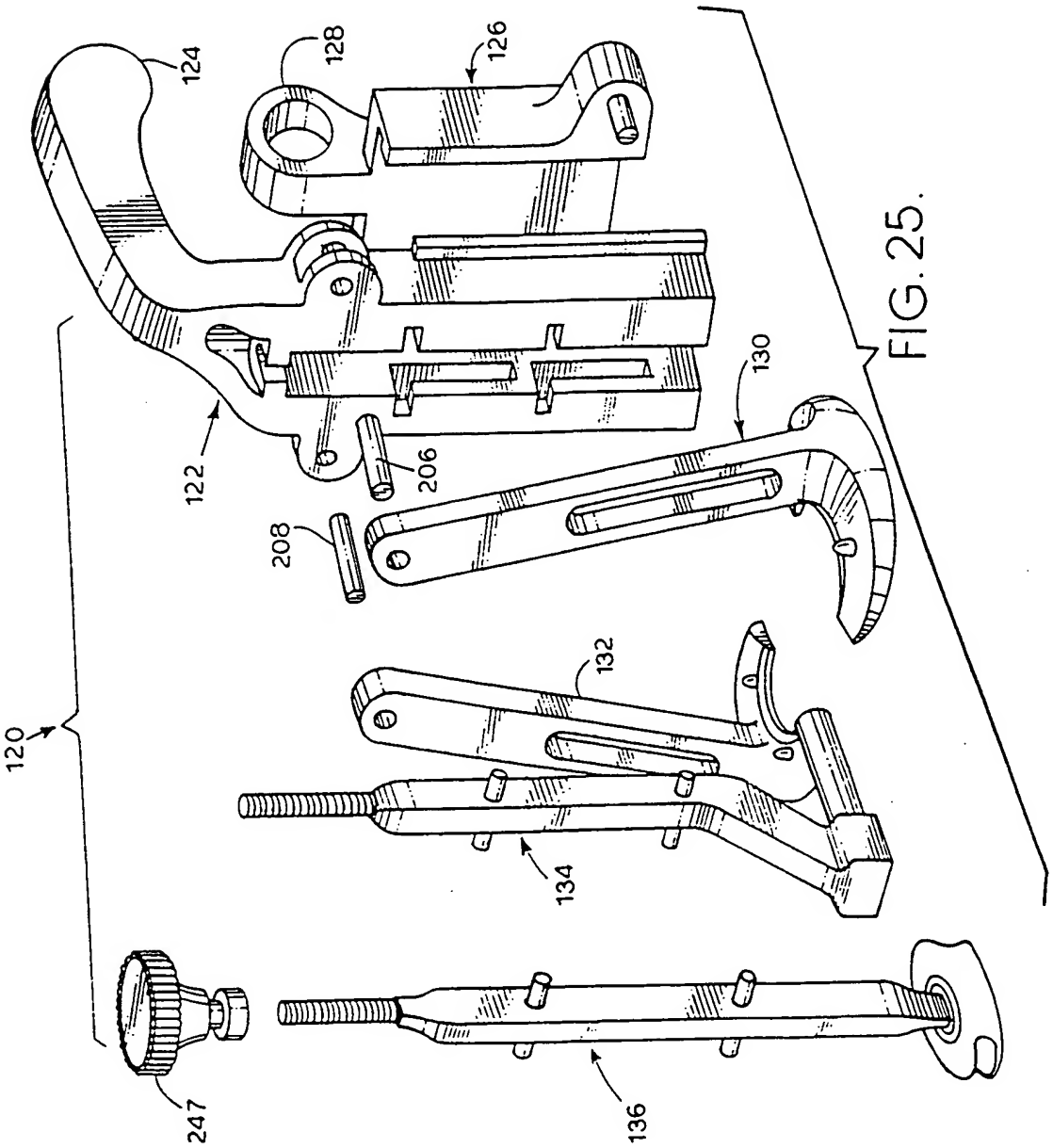


FIG. 25.

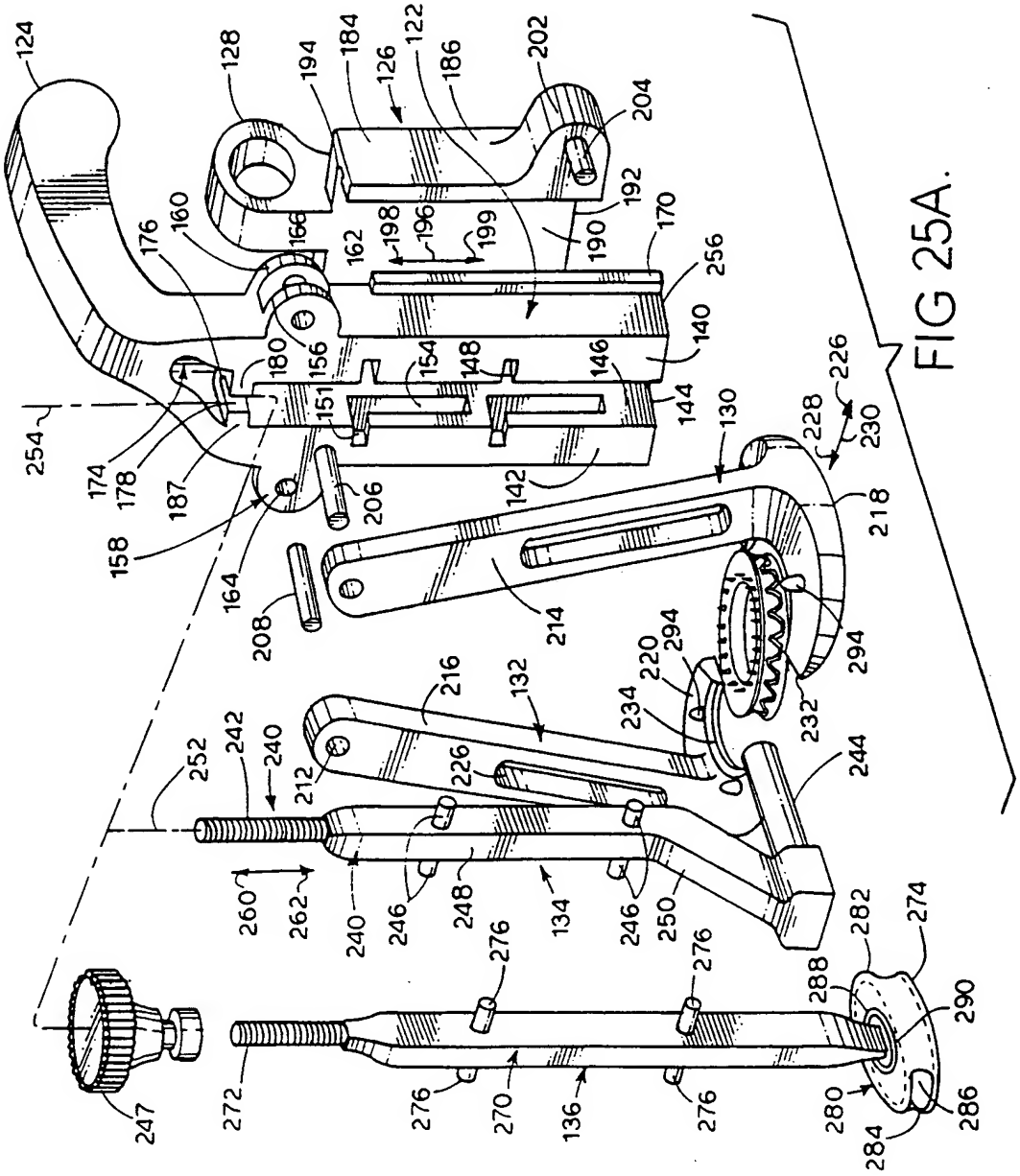


FIG 25A.

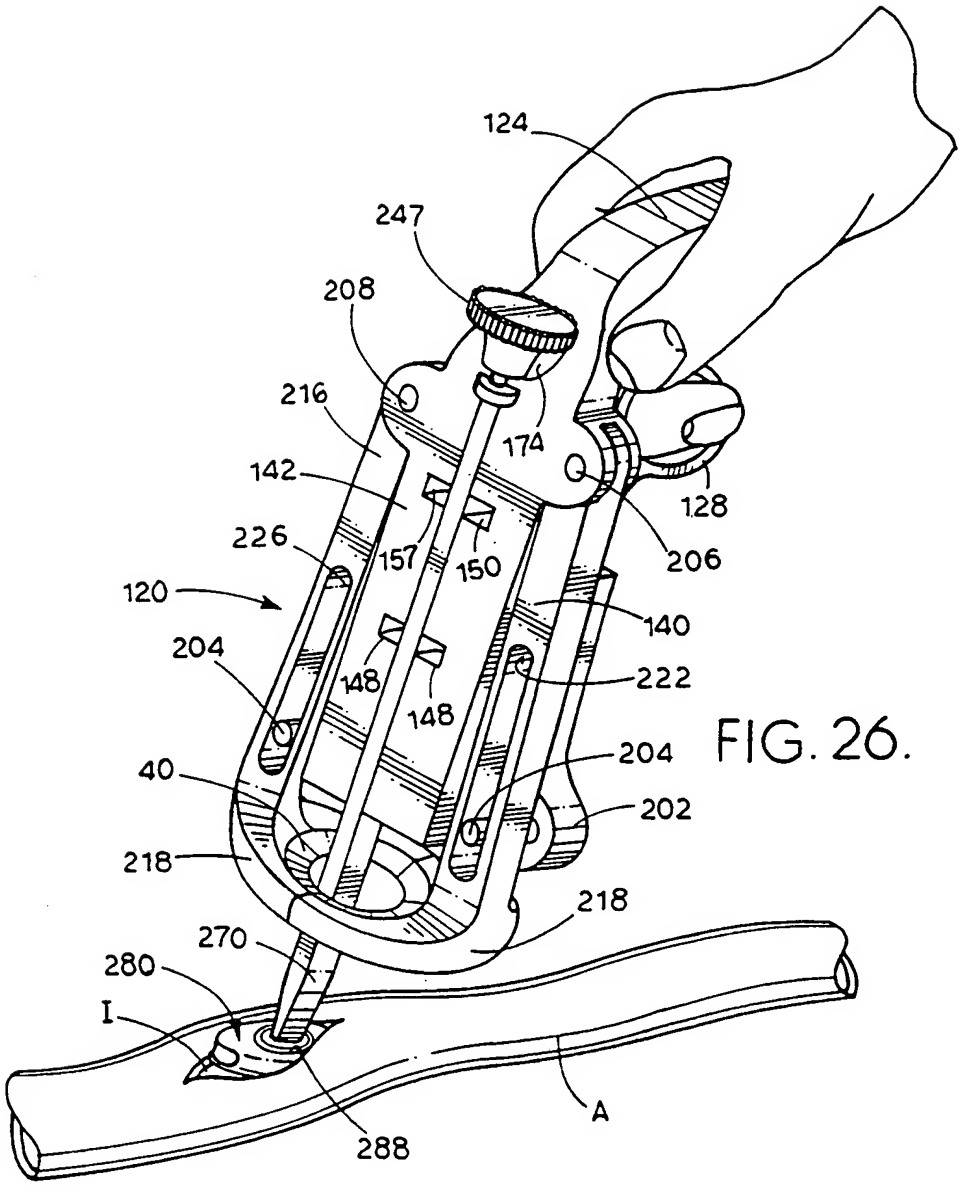


FIG. 26.

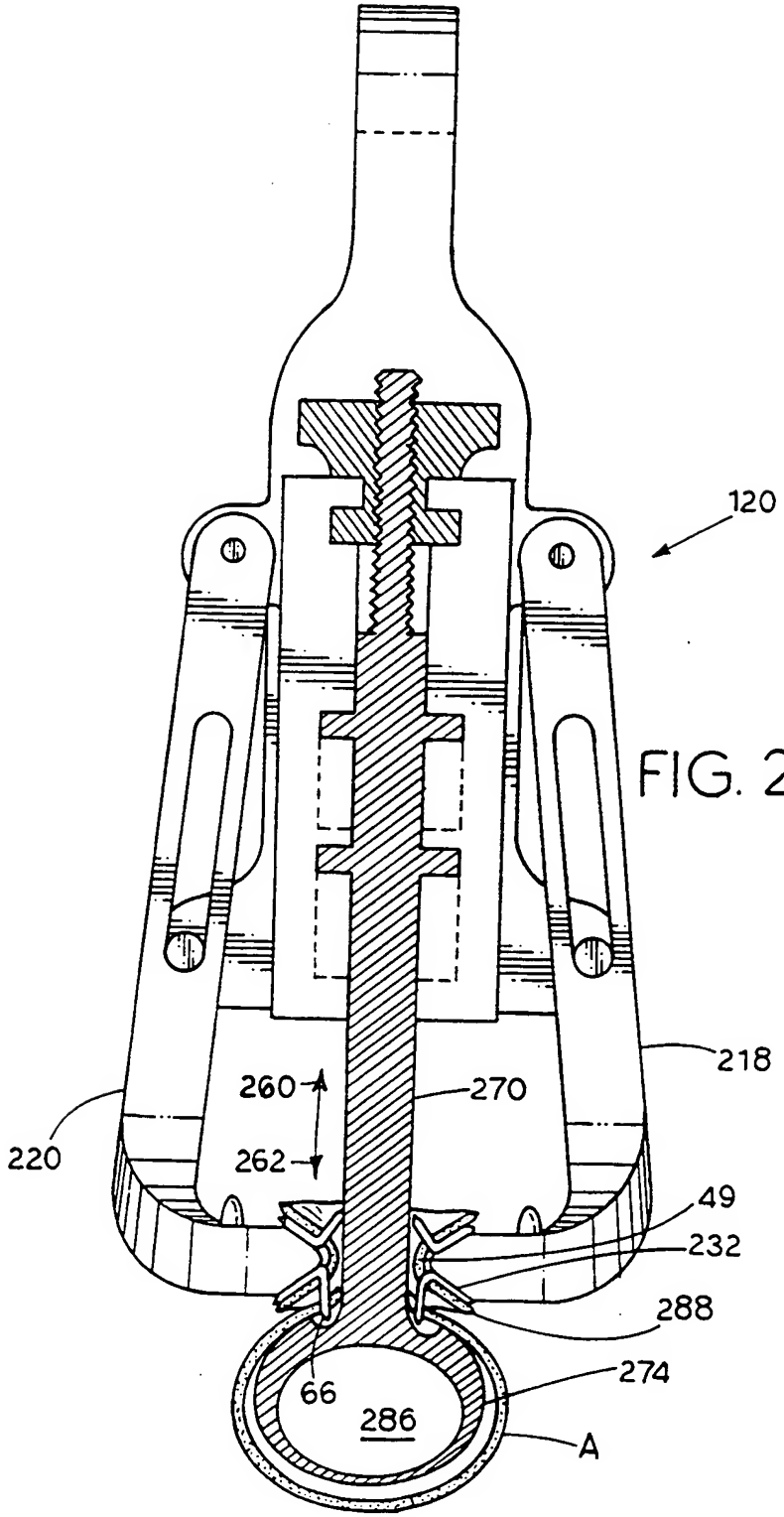
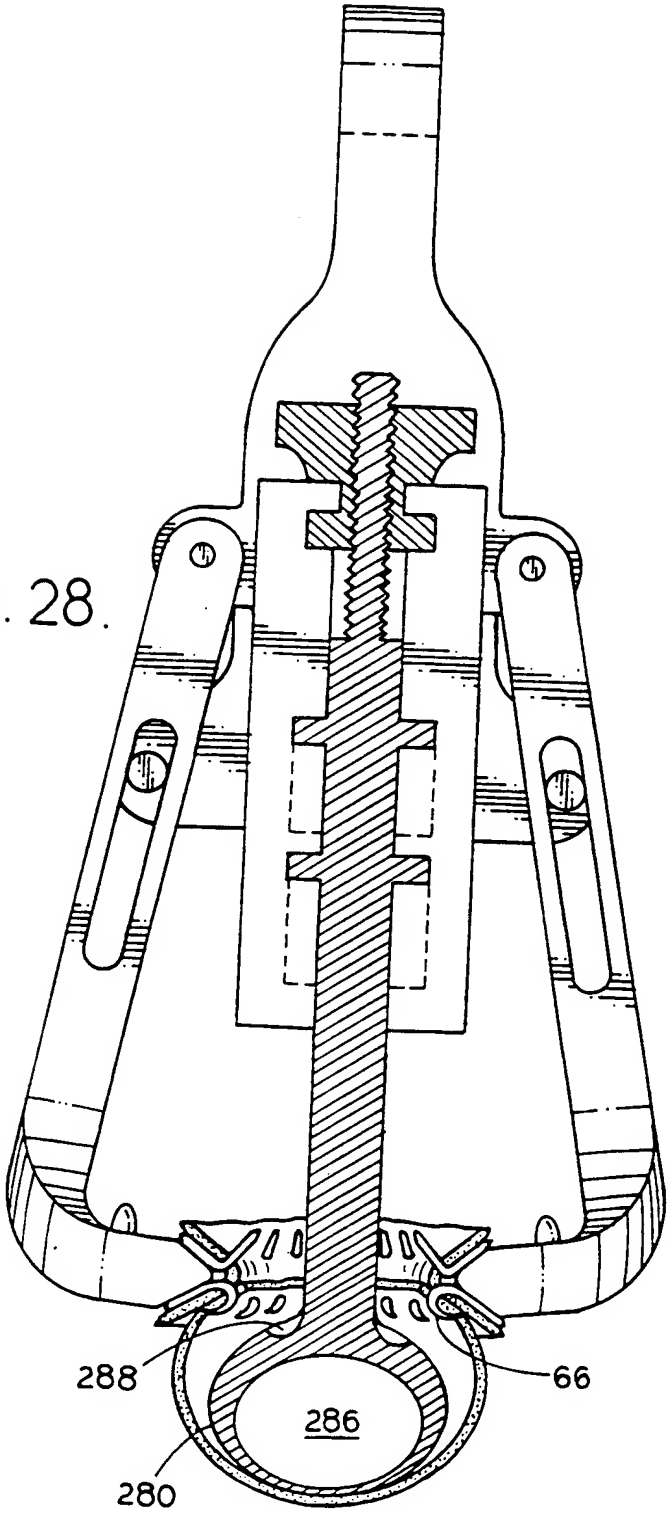


FIG. 27.

FIG. 28.



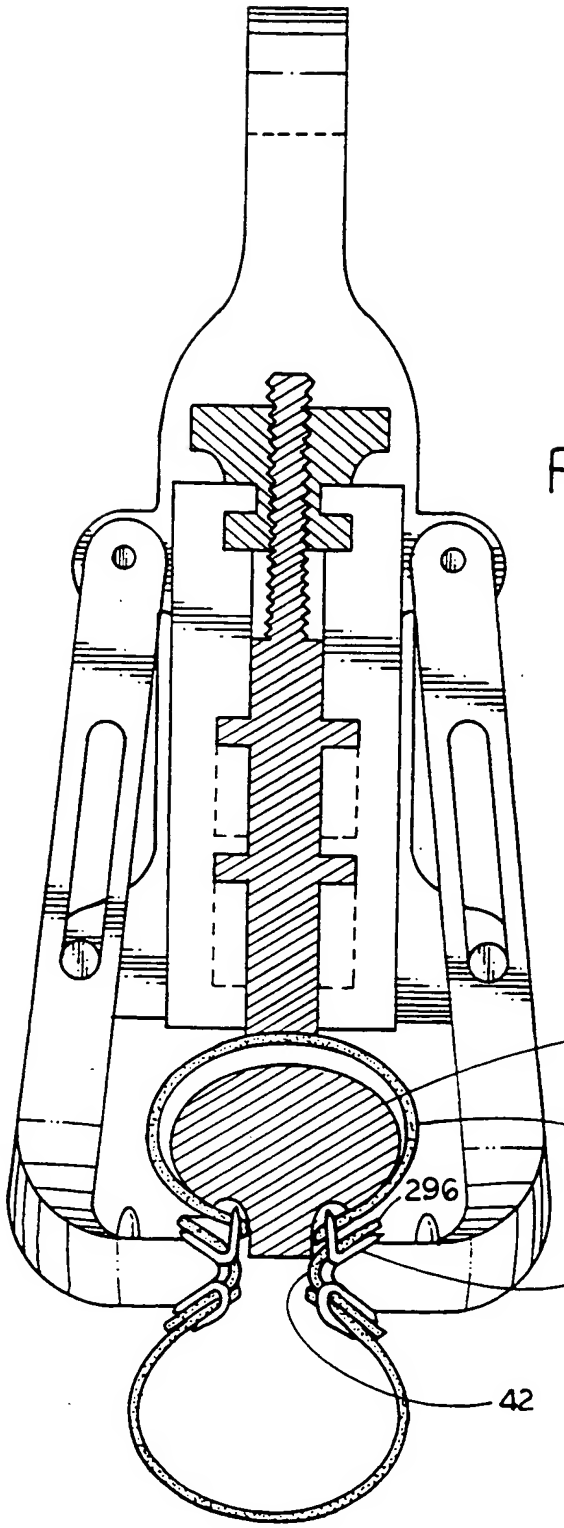


FIG. 29.

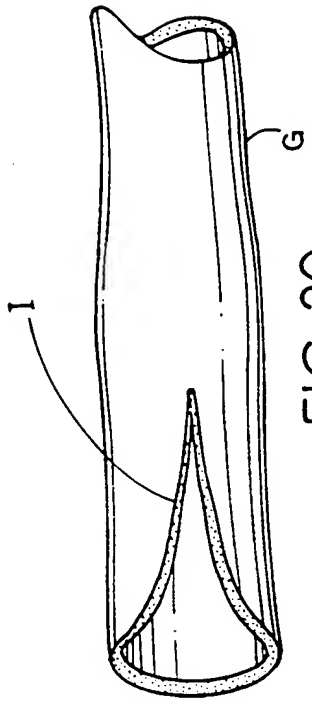
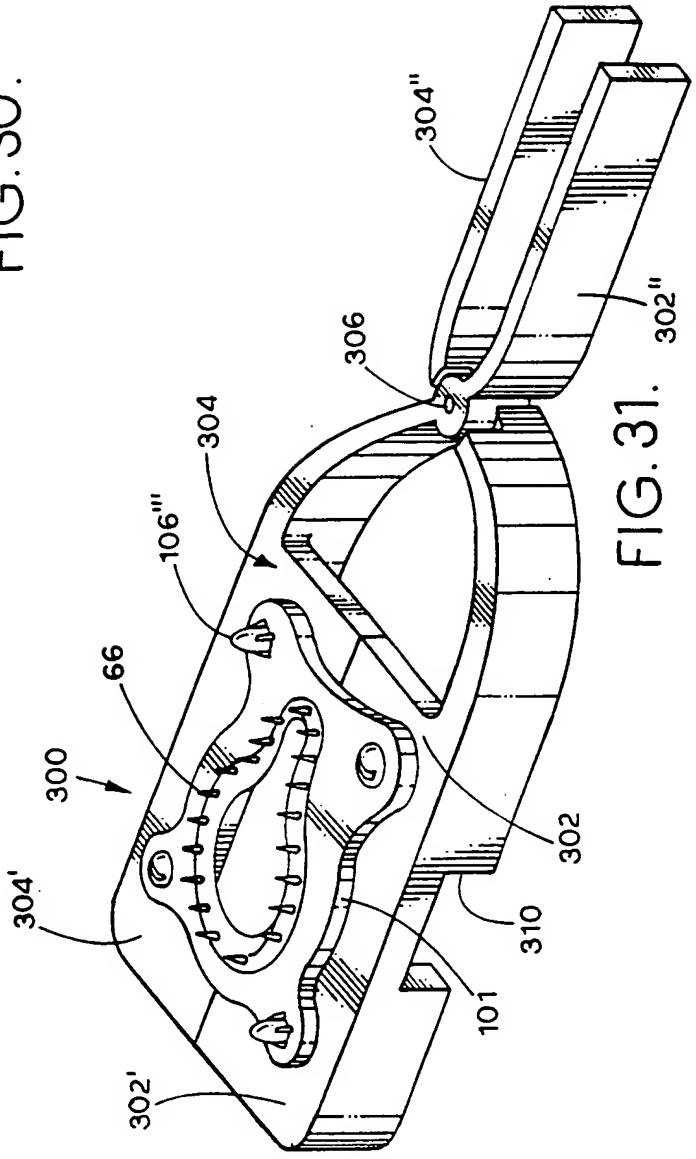


FIG. 30.



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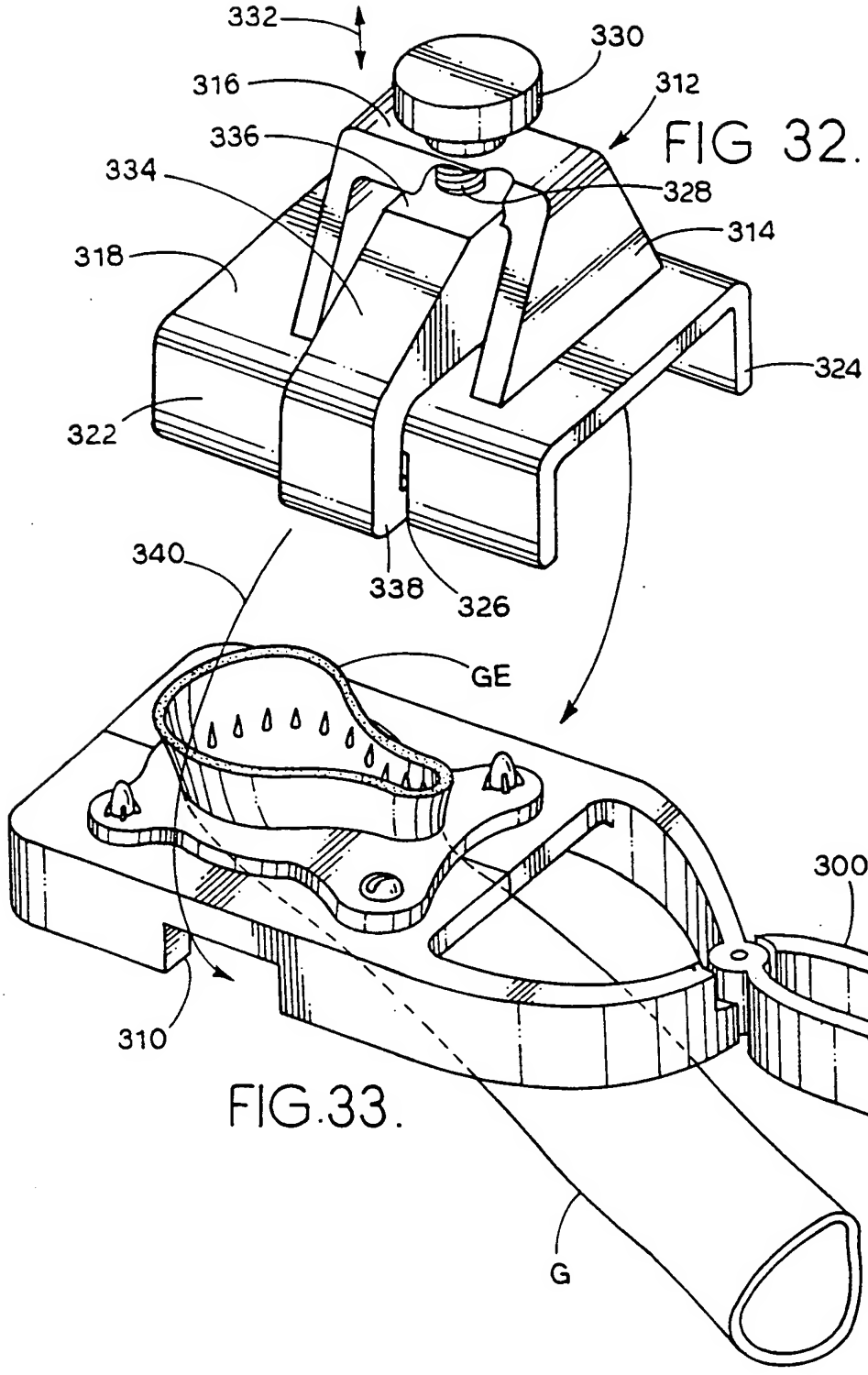
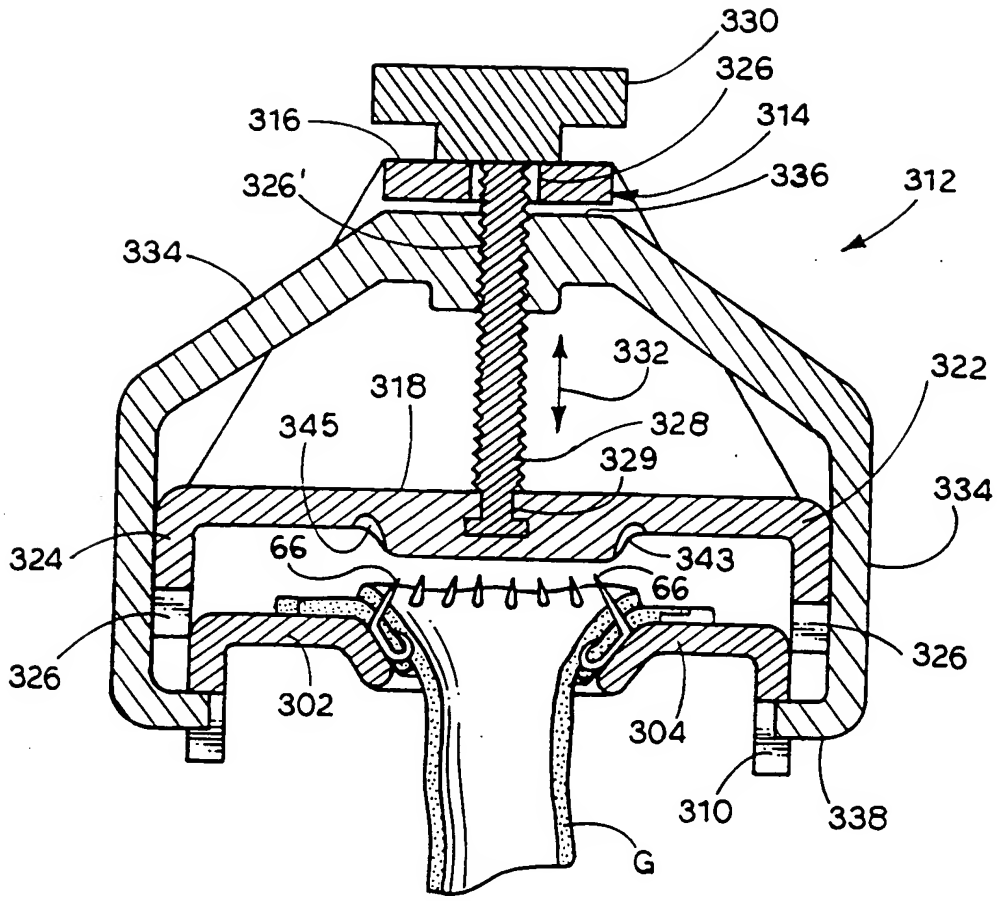


FIG 32.

FIG.33.



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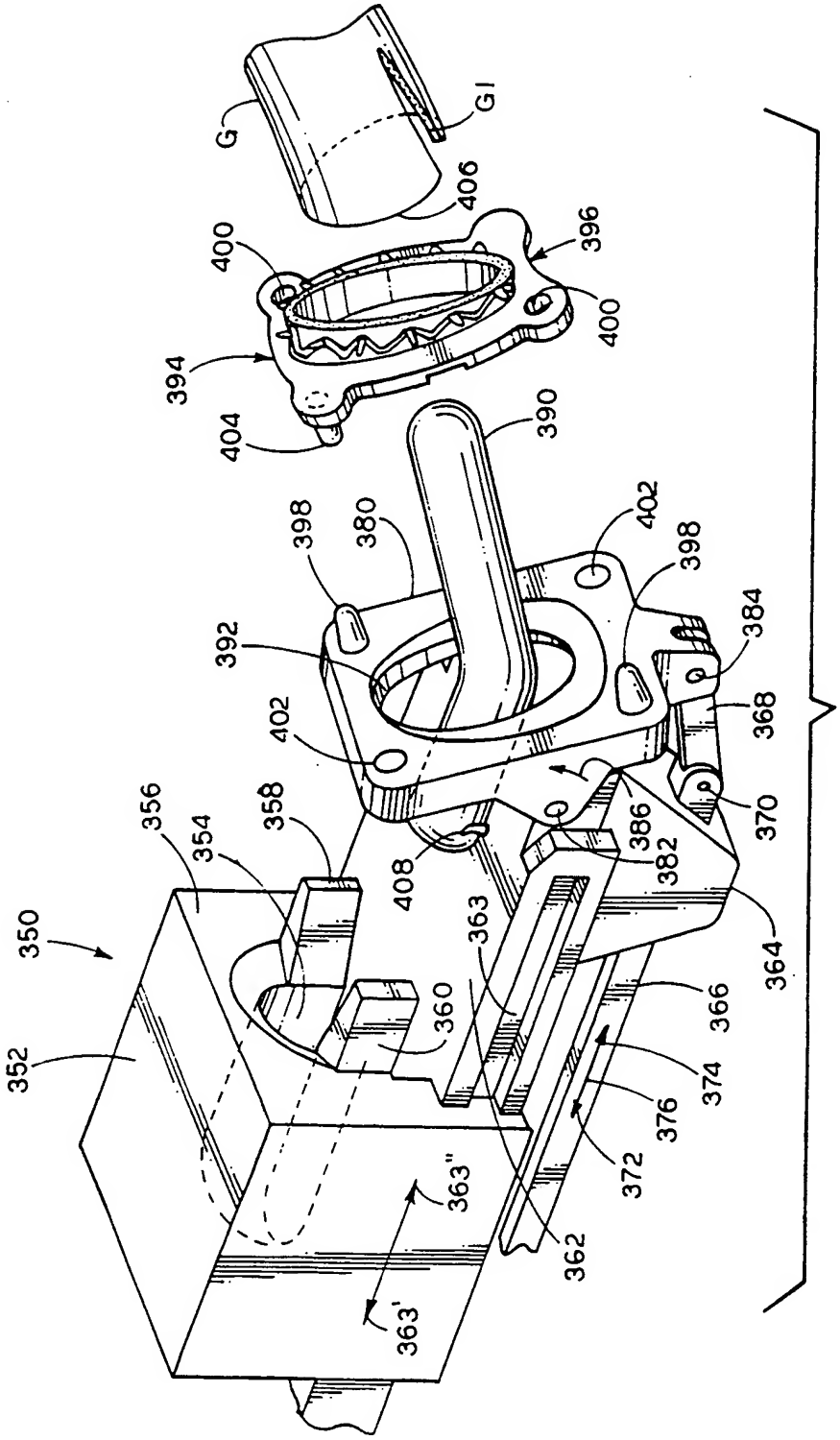


FIG. 35.

FIG. 36A.

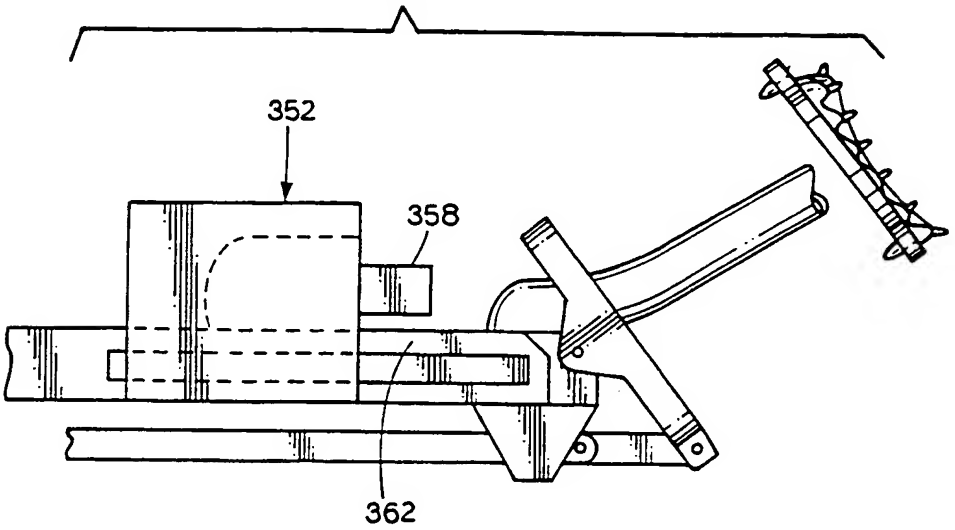
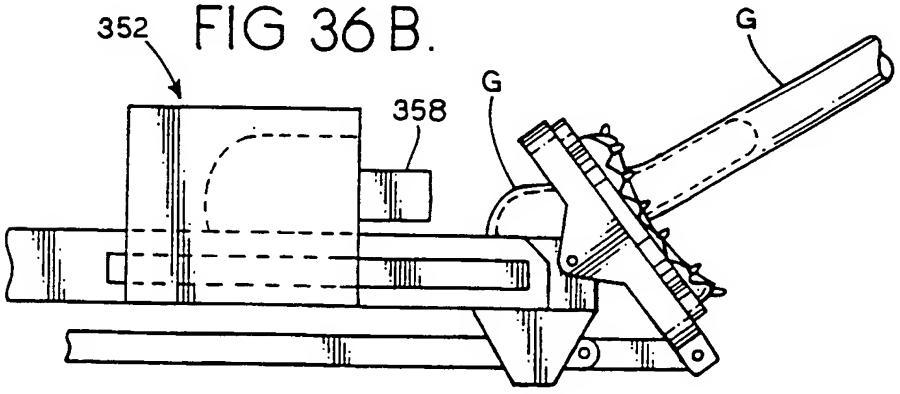


FIG 36B.



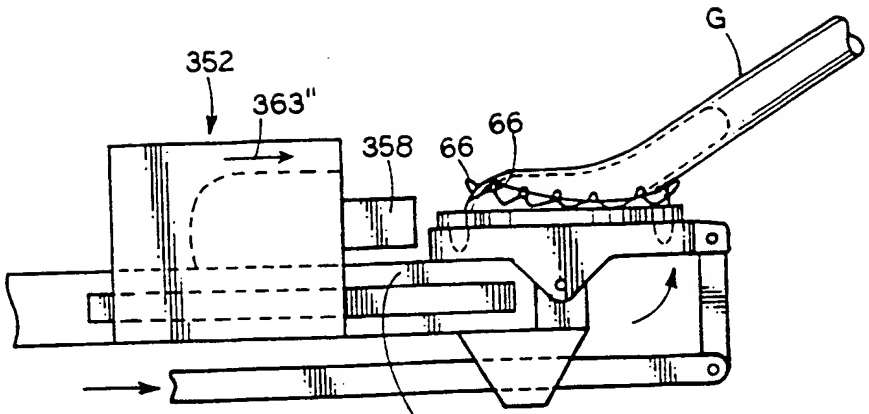


FIG. 36C.

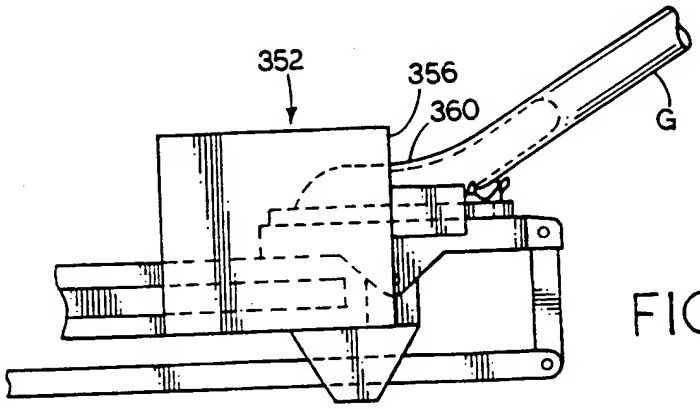
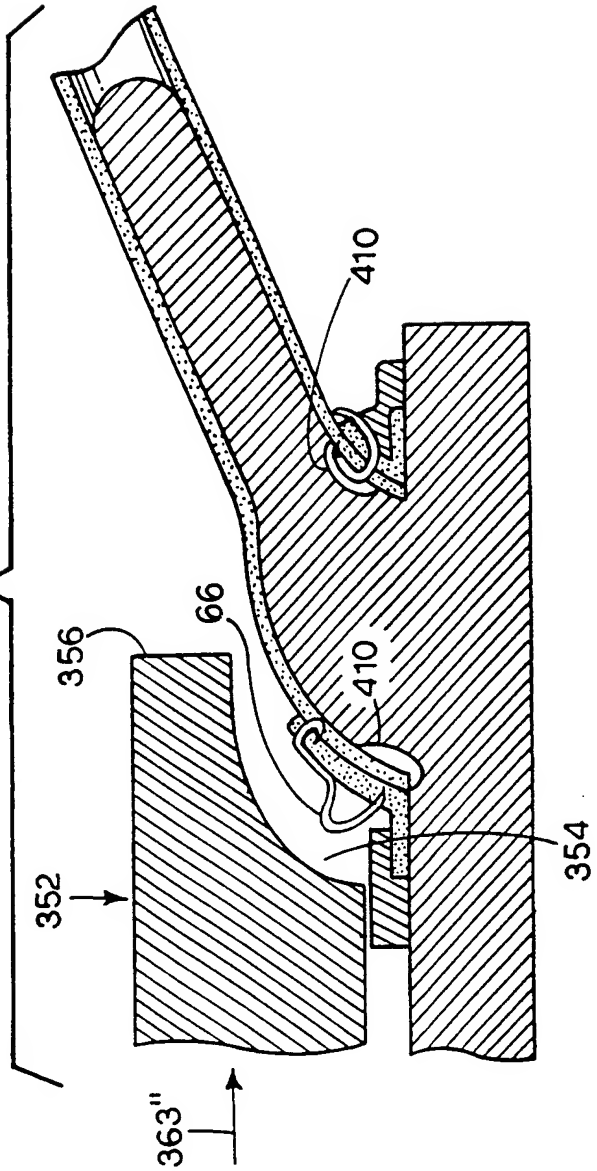


FIG. 36D.

FIG. 37.



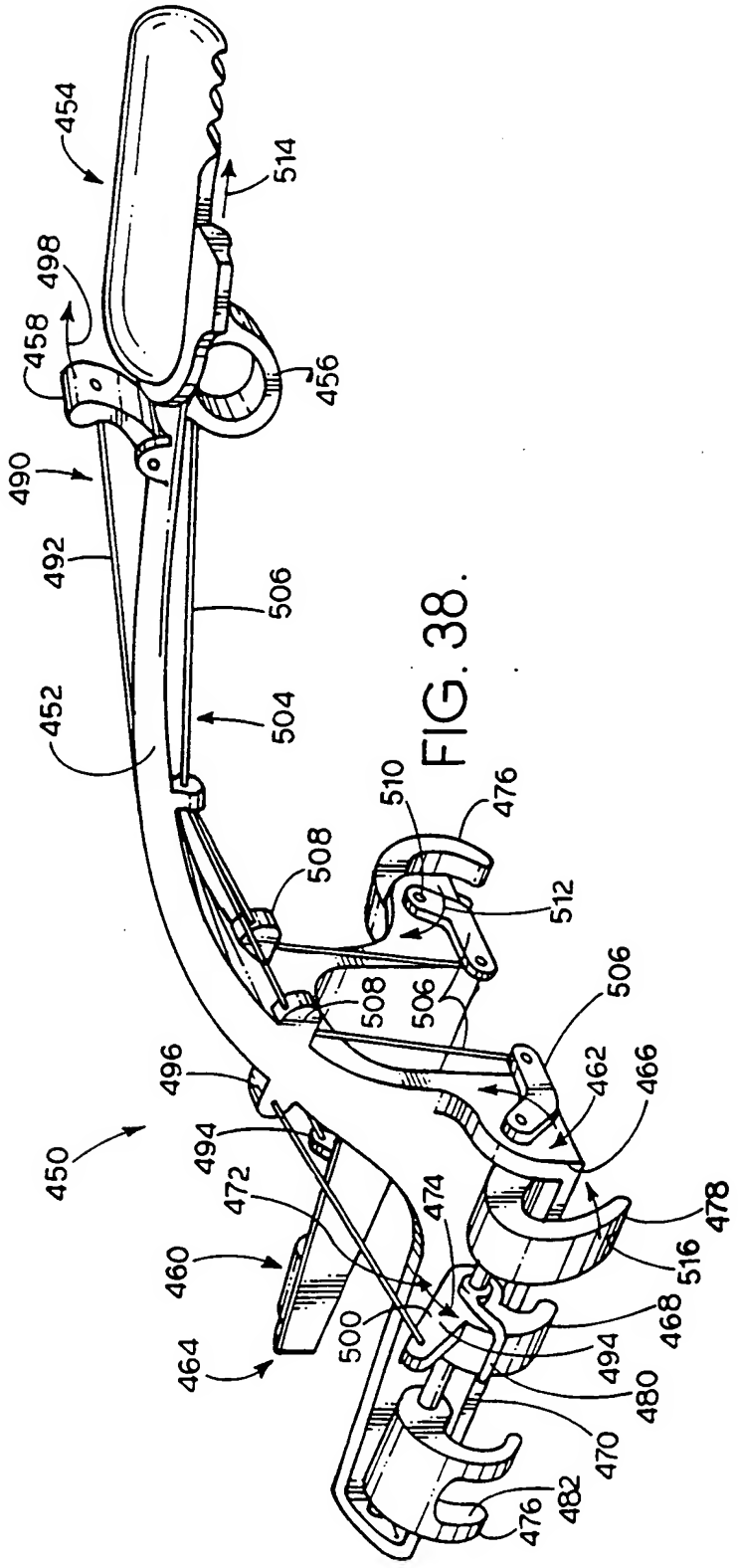


FIG. 38.

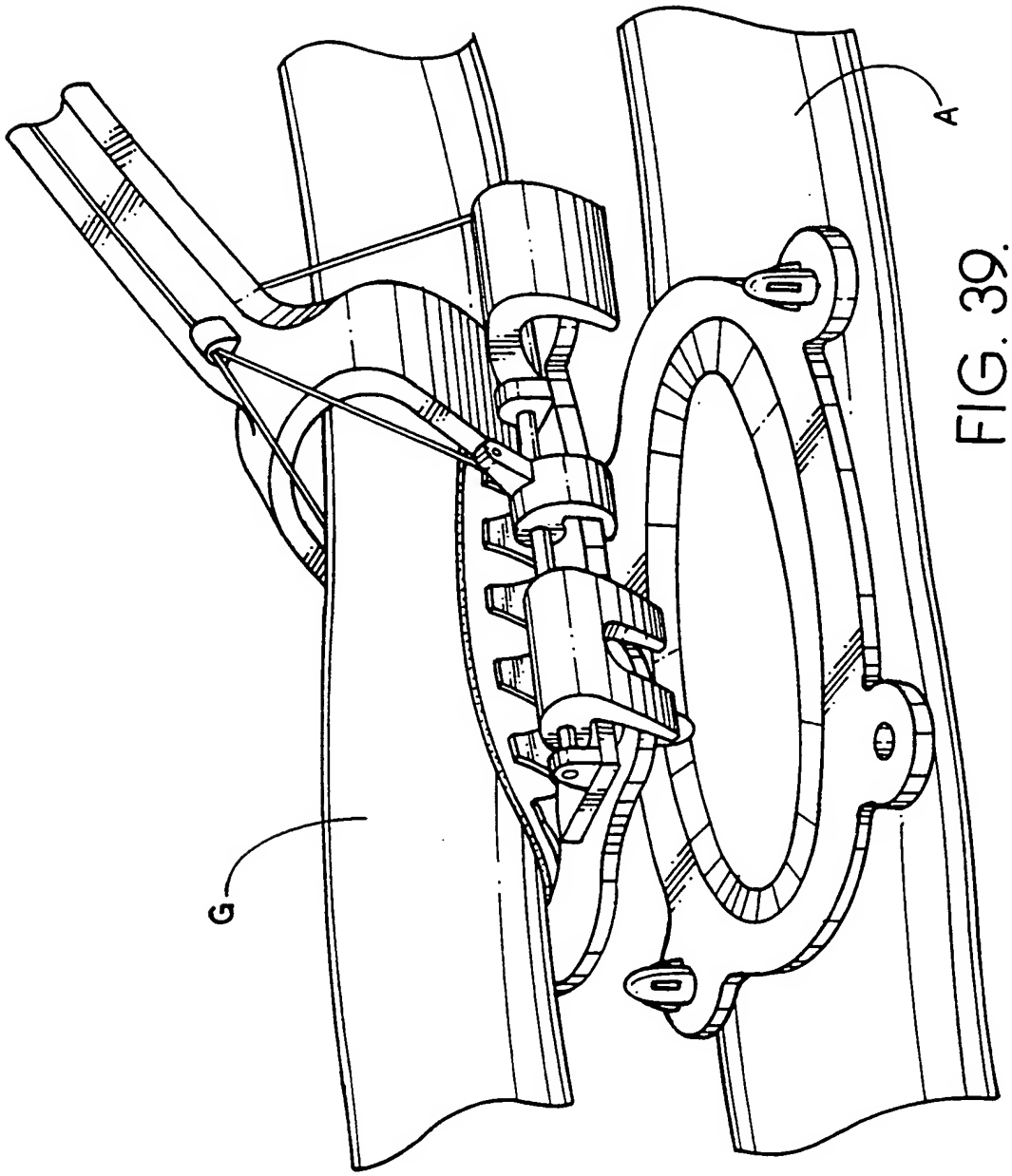


FIG. 39.

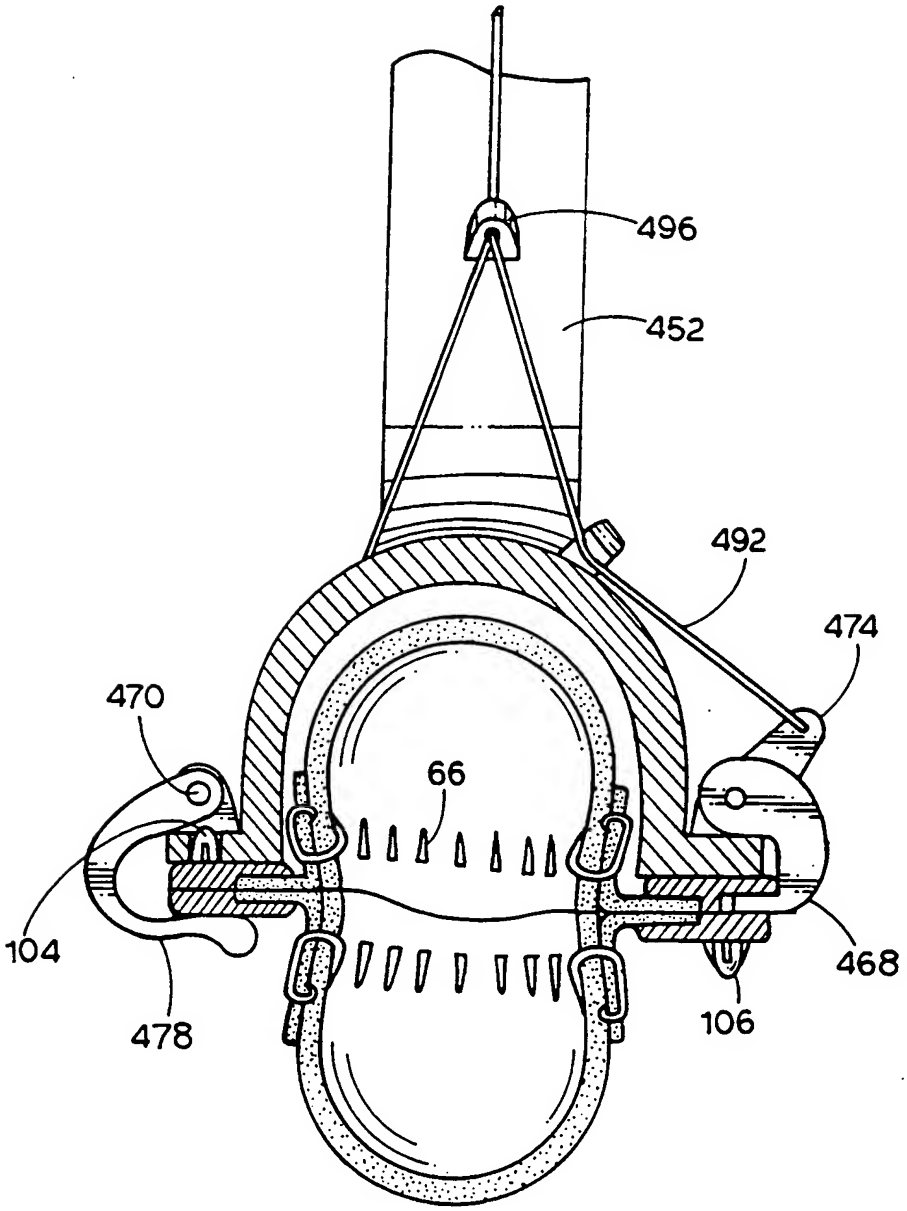


FIG. 40.

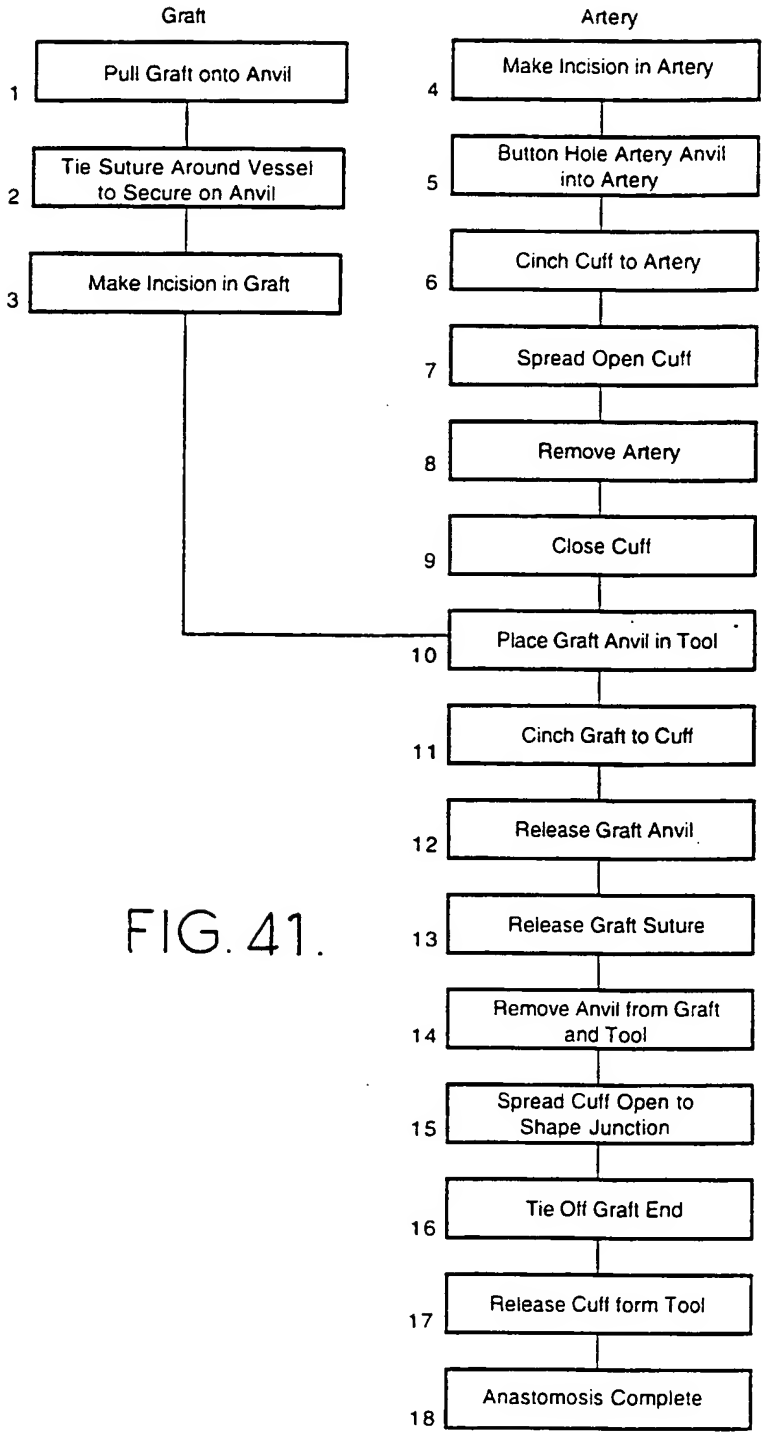


FIG. 41.

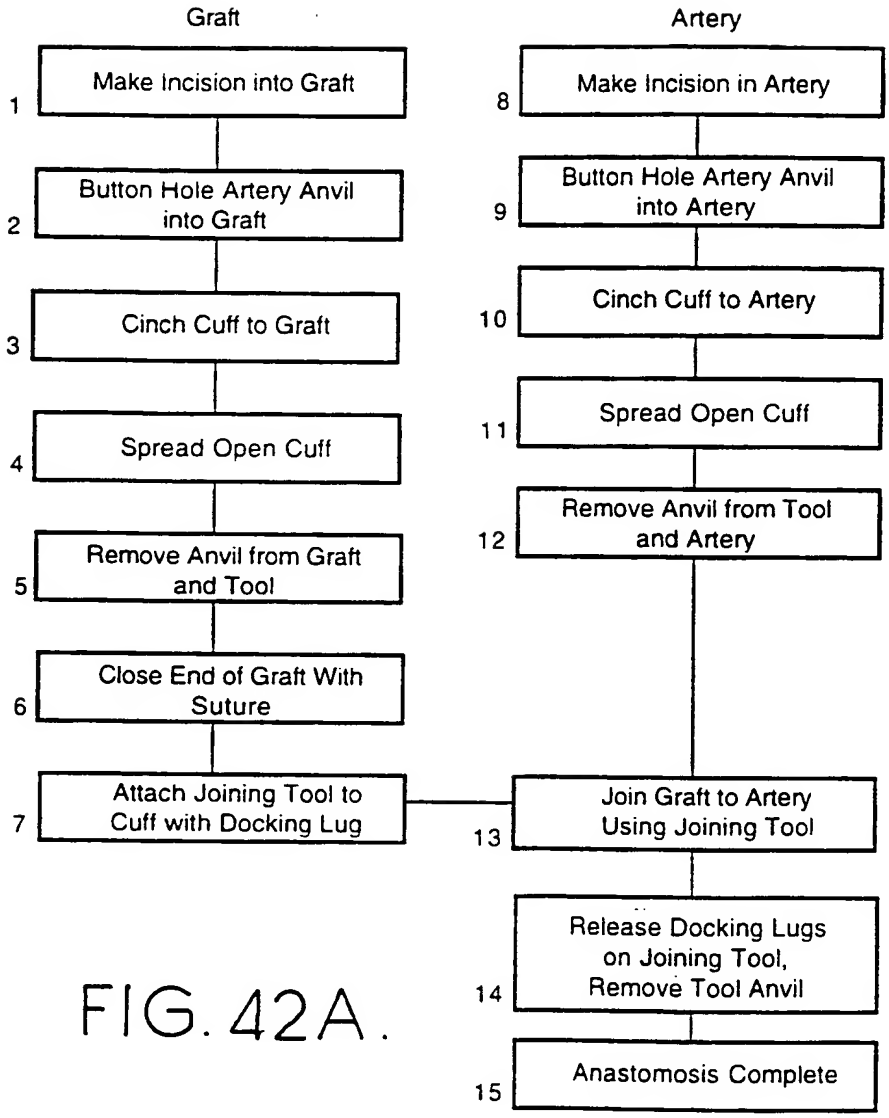


FIG. 42A.

FIG. 42B.

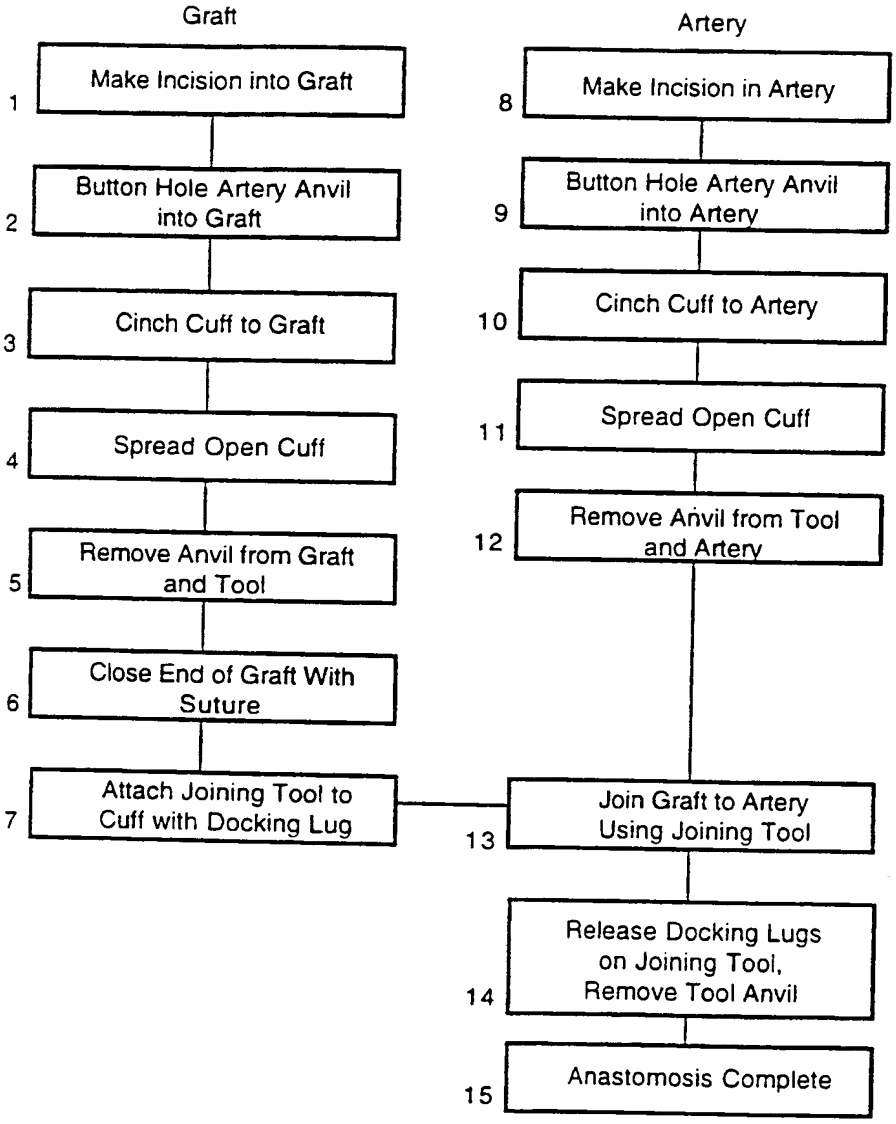
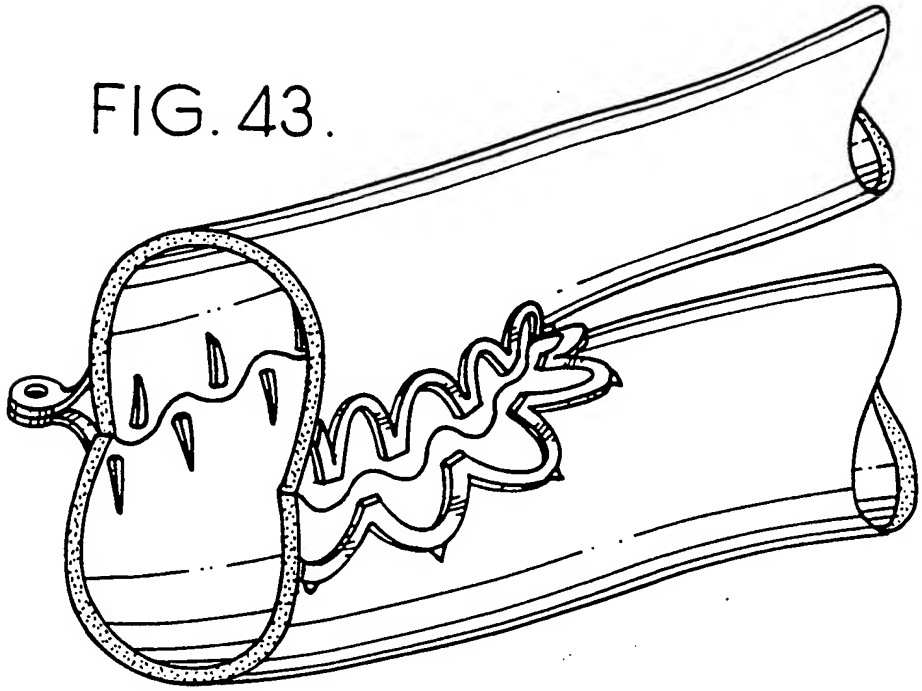


FIG. 43.



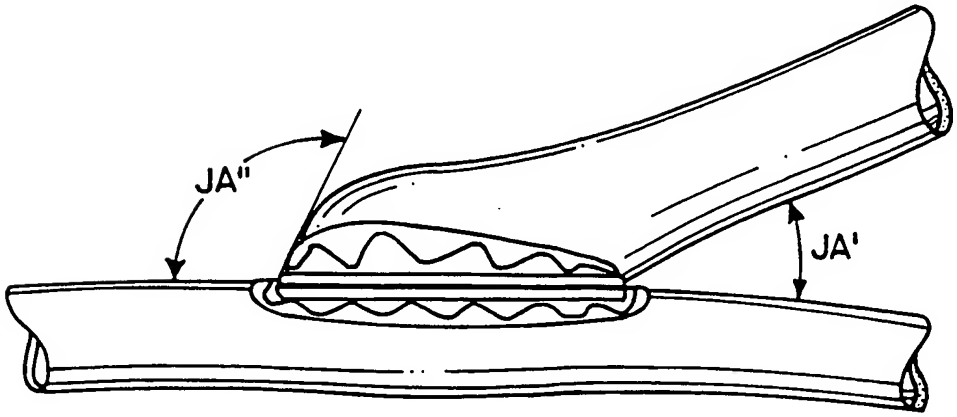


FIG. 44.

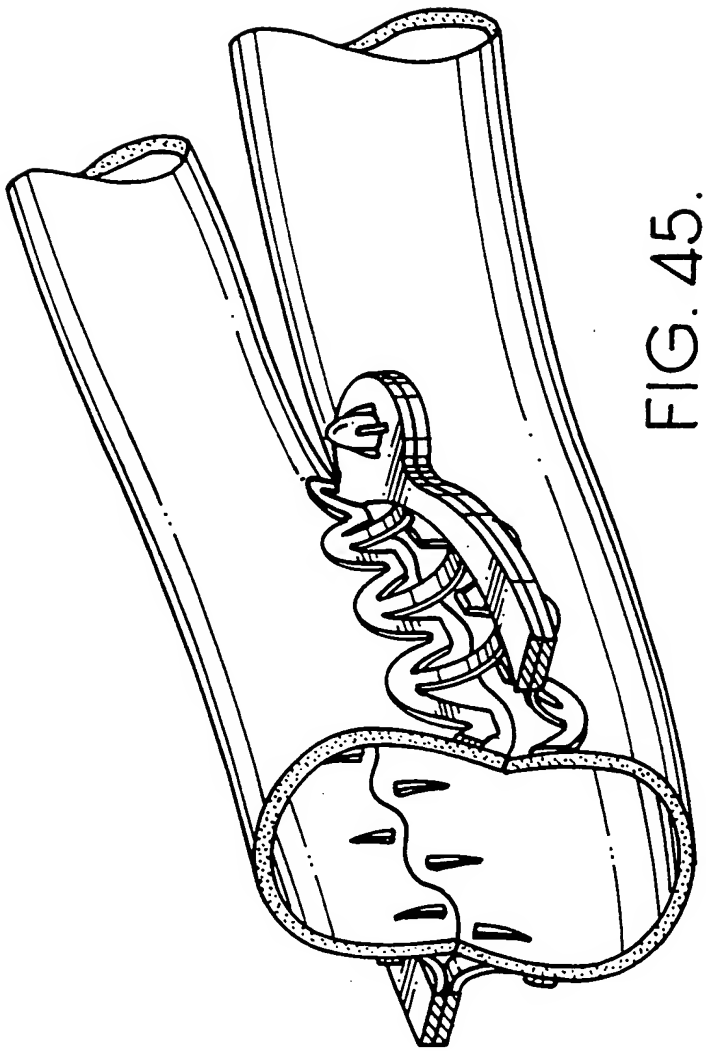


FIG. 45.

INTERNATIONAL SEARCH REPORT

Inter nal Application No
PCT/US 98/25874

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61B17/11 A61B17/115

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 7 A61B A61F

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 5 752 966 A (CHANG) 19 May 1998 (1998-05-19)	51
A	column 8; figures 9-11	1,2,12, 35,56,70

X	US 3 973 570 A (RAZGULOV) 10 August 1976 (1976-08-10)	20
A	figures 1,2,8,9	35

X	US 5 234 447 A (KASTER) 10 August 1993 (1993-08-10)	20
A	figures 1,10	2,35,70

X	DE 15 66 136 A (PFAU-WINFRIED) 12 February 1970 (1970-02-12) figures 7,8	20

	-/--	

[X] Further documents are listed in the continuation of box C.

[X] Patent family members are listed in annex.

* Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
8 December 1999	28 12 1999

Name and mailing address of the ISA	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl. Fax: (+31-70) 340-3016	Barton, S

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Form PCT/ISA/210 (second sheet) (July 1992)

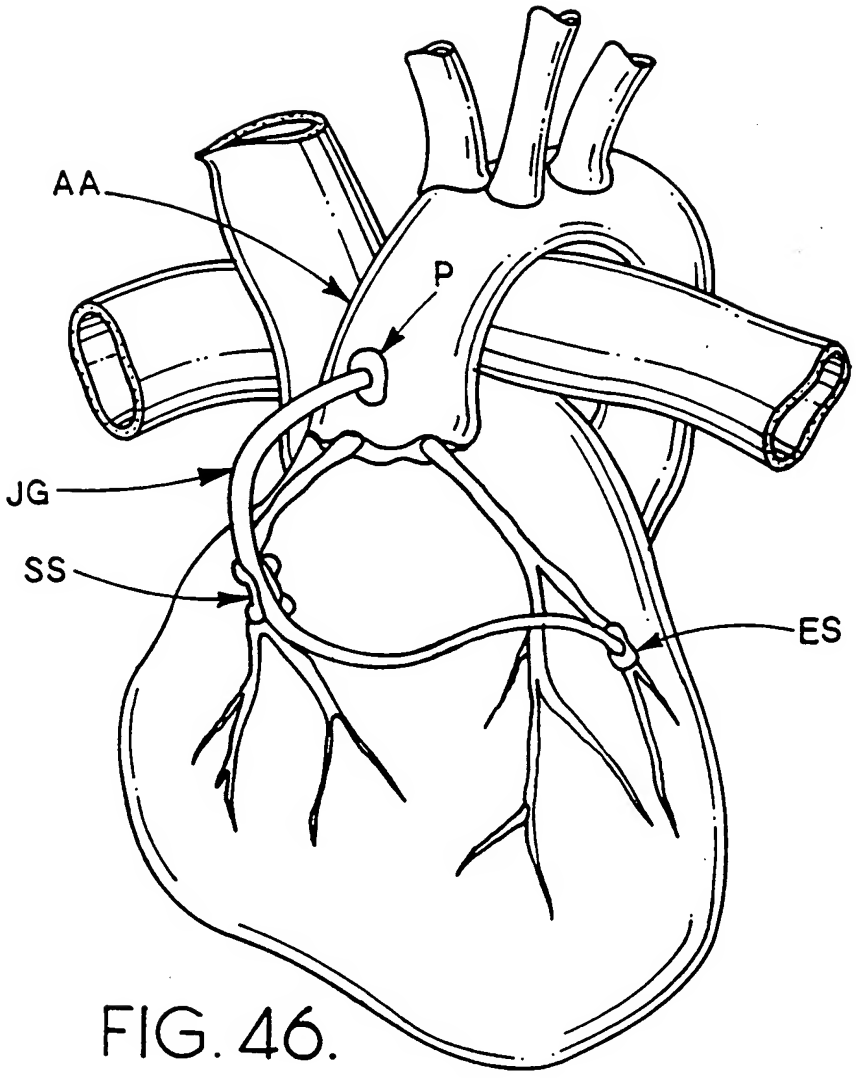

FIG. 46.

INTERNATIONAL SEARCH REPORT

Inter nal Application No
PCT/US 98/25874

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category	Citation of document, with indication,where appropriate, of the relevant passages	Relevant to claim No.
A	US 4 930 502 A (CHEN) 5 June 1990 (1990-06-05) figures 4,6,7	1,2,56, 70
A	WO 98 19630 A (VASCULAR SCIENCE) 14 May 1998 (1998-05-14) page 15, last paragraph -page 16, paragraph 1	1,56
A	WO 98 02099 A (HEARTPORT) 22 January 1998 (1998-01-22) figures 7,26	1,2,56, 70
A	US 4 747 407 A (LIU) 31 May 1988 (1988-05-31) abstract; figures 1,2	1,56
A	US 4 214 587 A (SAKURA) 29 July 1980 (1980-07-29) figures 3,6,7	56
A	EP 0 303 767 A (WALSH) 22 February 1989 (1989-02-22) figure 23	2,70
A	US 3 938 528 A (BUCALO) 17 February 1976 (1976-02-17) figure 6	35,51
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A	US 3 974 835 A (HARDY) 17 August 1976 (1976-08-17)	
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A	US 5 188 638 A (TSAKIS) 23 February 1993 (1993-02-23)	

3

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US 98/25874

Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. [X] Claims Nos.: 34,36-38,40-50,68
because they relate to subject matter not required to be searched by this Authority, namely:

Rule 39.1(iv) PCT - Method for treatment of the human or animal body by surgery

2. [ ] Claims Nos.:
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:

3. [ ] Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

see additional sheet

1. [X] As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.

2. [ ] As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.

3. [ ] As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:

4. [ ] No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

[ ] The additional search fees were accompanied by the applicant's protest.

[X] No protest accompanied the payment of additional search fees.

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

This International Searching Authority found multiple (groups of) inventions in this international application, as follows:

1. Claims: 1,3-10,14-16,18,29-31,56-59,73

   Anastomosis device with means for defining shape of the junction lumen

2. Claims: 2,11,17,19,32,33,39,52,60-65,70-72,74

   Anastomosis device with stiffening framework for bringing the incised surfaces together in a controlled manner

3. Claims: 12,13

   Anastomosis device for side to side anastomosis

4. Claims: 20-28

   Anastomosis device applier

5. Claims: 35,51,53-55,66,67,69

   Anastomotic stent for exovascular use, and applier

INTERNATIONAL SEARCH REPORT

Information on patent family members

Inter ɔnal Application No
PCT/US 98/25874

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INTERNATIONAL SEARCH REPORT

Information on patent family members

Inter. nal Application No
PCT/US 98/25874

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